elw

ELWDEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

APPLE CIDER FOOD SAFETY CONTROL WORKSHOP VOLUME II

Friday, July 16, 1999

8:30 a.m.

Room 305A
Hubert Humphrey Building

MILLER REPORTING COMPANY, INC.
507 C Street, N.E.
Washington, D.C. 20002
(202) 546-6666

elw

200 Independence Avenue, S.W.
Washington, D.C.

MILLER REPORTING COMPANY, INC.
507 C Street, N.E.
Washington, D.C. 20002
(202) 546-6666

C O N T E N T S

P R O C E E D I N G S

MR. SCHWALM: I'd like to welcome you all back this morning. We'll try to get started here.

You've heard about the best-laid plans of mice and men. When we rearranged our schedule yesterday, the lady that was supposed to talk about labeling, and she said, "Well, you know, I can come back tomorrow, since it's at the end of the day." I said, "Are you sure you can come back tomorrow?" She said, "I'm sure, and if I can't, I've got a back-up person and I'm sure that back-up person can come."

Well, I had a message on my phone today that neither one of them could come at 8:30 this morning. However, we do have a life-saver, and I'm not sure how it was arranged. The airlines, I guess they actually arrived early or something. I don't quite understand it. Maybe our next speaker will go into that, I don't know.

But our second speaker on the agenda, Dr. Shaffner from Rutgers, who is going to be talking about risk assessment, is here with us and most graciously agreed to come early, to go on early, which will be really better because there have been a lot of questions about risk assessment, and I don't think anybody else is going to be here until at least 9:00, so we'll have a

little extra time to discuss risk assessment with Dr. Shaffner.

DR. SHAFFNER: Well, thank you very much, Darrell, and thanks for inviting me to be here to talk about the work that we're doing with our risk assessment for E. coli 0157:H7 in apple cider.

I want to mention, before I get started with my remarks, that this--as with all risk assessments, but in this particular case as well--this is a work in progress. This is research that has come out of our heads and the scientific literature, and it has not been through the peer review process yet. I'm hopefully giving you some examples of some of the pieces of--I will give you some examples of some of the pieces of what we have done, but until it has actually been through the peer review process and some folks other than the two of us who have been involved with this have looked at it, you need to take it somewhat with a few grains of salt.

So, with that, let me get started. I do also want to acknowledge my co-author, who is here, Siobain Duffy. It's really Siobain that has done a lot of the leg work, and also a great deal of the brain work as well, putting this risk assessment together.

First of all, before we get started, let me try to explain to you in a few words what we believe a

quantitative risk assessment is. It's a blend of the published scientific literature, expert opinion--and expert opinion, linked together by a computer simulation. You can also think of it as being an organized warehouse of data on a particular topic. You can also think of it as being a summary of the influence of specific factors on the overall safety of a food product, for example. We also believe that risk assessment can be a science-based, cost-effective way to estimate risk.

When we started with this project, we asked ourselves, "Well, why would we want to use a quantitative risk assessment framework for looking at the issue of E. coli 0157:H7 in apple cider? Well, first of all, quantitative risk assessment is nice because it's quantitative. It allows us to combine data that we have collected from different laboratories or different experiments or different experts, even.

The thing that I really like about quantitative risk assessment is that it incorporates the variability and the uncertainty in the data itself, and in the differences of opinion from, let's say, different research papers, and all of that is incorporated into the risk assessment. Oh, I also want to say I see a few of you taking notes. I apologize, I didn't bring handouts and there are no handouts for my talk in the binder.

However, if you give me your business card sometime this morning, I'll be here for the rest of the morning, give me your business card, I'd be happy to send you a copy of my remarks here by mail.

Another key feature of quantitative risk assessment is that it's customizable for individual producers' needs. One of the reasons we got into this project was, we were interested in answering the question, "Well, if we want to achieve a 5 log reduction of 0157:H7 in apple cider, and we don't want to pasteurize, are there other techniques that perhaps considered individually might not give a 5 log reduction, but considered together, would?" We looked at quantitative risk assessment as an approach to seeing, at least from a computer simulation point of view, whether that would work.

Finally, we believe quantitative risk assessment can be extremely useful when it's integrated with HACCP, because what quantitative risk assessment allows you to do is to identify those factors in your process that really should be critical control points in a HACCP program.

When we started, we asked ourselves, "Well, what could be part of a quantitative risk assessment?" Well, we could include information on pre-harvest conditions,

manure, animal contamination, the use of dropped apples, transmission or spread of 0157:H7 by fruit flies, differences in--cultivar differences in terms of pH and other factors. We can look at processing factors like the water, washing, brushing, equipment contamination and sanitation, pasteurization, other types of sources of contamination as well. And, finally, we can look at the effects of storage conditions, things like preservatives, temperature of storage, freeze/thaw cycles, and time to sale, all as being factors in this risk assessment.

What do you get at the end of day when you're finished with your risk assessment, or at the end of the year when you're finished with your risk assessment? Well, one of the most important things that I think comes out of it is a conceptual framework for thinking about the problem. We may not have all the answers when our risk assessment is done, but at least we have done hopefully a good job of framing the question. Then we can come along and fill in more details as we learn more about the scientific underpinnings of this particular topic.

We also have the computer simulation, which is a dynamic model of a particular food system, food processing and storage system, in this case a simulation

of the numbers of E. coli 0157:H7 in apple cider as a result of various processing conditions.

Another important result of the--at the end of the day when you're finished with your risk assessment is some sort of a sensitivity analysis. "Sensitivity analysis" is a statistical term for a concept that says "What are the factors that are most important?" If I have 10 or 15 variables that are under my control, which are the five that are most important? Again, this gets back to--this is starting to sound a little bit like HACCP--this gets back to identifying those critical control points, those points in the process where you really want to be sure that you're in control.

Finally, I think any risk assessment is going to result in some ideas on avenues for future research. One of the things that's so important in risk assessment is characterizing the variability and uncertainty of the data, and if you have particular points in the process where there's a lot of uncertainty and there's a lot of variability, well, that might be one place. If the uncertainty is not because of the inherent variability of the numbers but is just uncertainty in our knowledge about what happens in that part of the process, then that would be a place to go for future research.

So a well-done quantitative risk assessment will identify avenues for future research, and identify data gaps as part of that. What are some data perhaps that we wanted to include in our risk assessment, and you'll see an example of that on a slide near the end, something you'd really like to know about, that we really think might have an influence, but we just don't have any good data?

And hopefully, again, if some of you become interested in this idea and have data or have ideas for our risk assessment, I'm here today at the invitation of the FDA to talk to you, but I really hope that we can learn as much from you about how to further guide and direct our risk assessment, as much as you learn from me.

I apologize for the poor quality of this slide. This shows a screen snapshot from the program that we're using to develop the risk assessment. It's a piece of software called Analytica, and that's what you see over here. This is the Analytica screen snapshot.

If you want to take a look at the risk assessment sometime this morning, I brought my computer which has the actual functioning risk assessment and the Analytica program, and so that's going to be over at that laptop over on that side of the room. So if you want to come by later and play around, I know you can't really

read any of these things, but it includes inputs like the size of the orchard, number of apples per acre, the presence of landfill or ocean, which we know influences the occurrence of 0157:H7 in bird droppings, and again a whole variety of other factors that you can play with, as well.

One of the very nice things about using this piece of software called Analytica is that once we develop the risk assessment, we can distribute it to whoever is interested. You can download a free reader for the Analytica program, much like those of you who are familiar with the Internet and use Adobe Reader to read Adobe documents. Well, there's a reader for this Analytica program, okay, the Analytica Reader, so that you can actually get a copy of the risk assessment and play around with it and input various factors and see how that influences the final end result.

So this is, again, a screen snapshot of what the user interface looks like right now. Right now, the risk assessment is composed of several modules. Each of the modules you see here is actually composed of some sub-nodes that influence, again, the way all the factors interact. And, again, if you want to take a look at the actual risk assessment, we can show you the data that underlies each of these notes.

And I apologize for the way the graphics are showing up here. When I look at it on my computer there's actually another arrow, and that leads from here down to here. But basically here are some of the factors and some of the ways the modules interact.

We know that even if you don't use drops, the fruit might theoretically become contaminated by bird feces, and we know that a certain fraction of bird feces has a likelihood of being contaminated with 0157:H7. We know that if you have animals in the orchard, that can influence the number of E. coli present on dropped apples.

We know that flume water or we suspect that flume water and the use of chlorine rinses can vary the microbial counts on the apples before pressing. We know the use of--or we suspect or we hypothesize in the risk assessment that the use of sanitizers can control 0157:H7 on the equipment. And we also know--we have a lot of information in this part of the risk assessment--that pasteurization, freeze/thaw, and the use of preservatives can all influence and indeed reduce E. coli counts in apple cider at the end of storage.

So basically the way it works is you have various assumptions, some of which are associated with certain degrees of uncertainty, and all of that feeds

through to that last module there, post-pressing processing, and the end result of that is the number of E. coli or the suspected range in the number of E. coli you find in the product.

I want to give you a look under the hood, so to speak, of a couple of different points in our risk assessment, to show you how we arrive at the data that constitute the risk assessment or the mathematical models or the assumptions that underlie the--that lie under the user interface.

We looked at, as one example, we looked at the influence of refrigeration on E. coli 0157:H7 in cider, in cider that doesn't have preservatives. And we went through the literature and we found five different papers, and you see those papers listed here, the Dingman paper at the top, the Zhao et al. paper at the bottom, and all the other ones in between. Okay? All of these papers had some data on the survivability of 0157:H7 in cider under refrigeration conditions ranging from 4 to 8 degrees C, and we sort of lumped all of those temperatures together based on some observations that we made.

What you find, if you look at all of those papers, is that most of the time over a one-day period the number, the count, the E. coli 0157:H7 count

decreases by a certain amount. Now, sometimes, just because of natural variability and who knows what, the count may go up some of the time.

So, what we did, we summarized all of this data from all of these papers as a histogram, and I'm going to show you the histogram in just a minute. And then we described that histogram with a statistical distribution, an equation. Okay? And then the way it works in the simulation is that every time you go to consider another day of storage of that apple cider, you pick another value from that distribution, and that represents what the E. coli do during that day time period.

So, here is the summary of the data from all of those five papers, and what you can see is that some of the time--a very low fraction of the time, because that's frequency on the long axis there--a low fraction of the time, you get about a 1 log decline in refrigerated apple cider containing 0157:H7 without preservatives.

Also, believe it or not, a similarly small fraction of the time you might see as much as a 1 log increase. This may be due to sampling errors, microbiological sampling errors. It may be due to survivability of the E. coli, perhaps even growth under some conditions.

And most of the time you see a slight decrease, because you can see the bulk of the curve lies to the left of the zero. So, most of the time, on average, you're going to see a slight decline. Some days you might see a slight increase. And we arrived at this particular figure using Excel spreadsheet software and its ability to generate histograms. We also used a computer program called Bestfit to come up with that normal distribution there.

That distribution, as I mentioned several times, described the log change that would occur in a single day. And what we do then, again for every day of that particular lot of simulated cider in our computer simulation, we pick a number from that statistical distribution, and that's what the E. coli does in that simulated piece of cider, that gallon of cider, on that particular day.

The other thing that I want to show you, and I'm sorry that Steve Ingham isn't here to see this, we looked at his paper from JFP earlier this year, and there is actually a nice little regression equation with a halfway decent R squared hiding in his data. We used a program called SAS to come up with a polynomial equation, just a simple empirical equation which described the influence

of the freeze/thaw process, holding temperature, time and pH to describe the log reduction of 0157:H7.

And you see these are the parameters for the equation here. There's two things that I really want to point out to you. First of all, the P values show that all of those factors are highly significant, which means that if you're going to try to control E. coli using freeze/thaw, all of these things become quite important.

So, what we did then is, if you choose in the risk assessment to use this freeze/thaw approach, you input the holding temperature, the pH of the cider, the hours at that holding temperature, and then you choose that you're going to go through this freeze/thaw cycle, and that will generate for you an estimate log reduction of E. coli 0157:H7 based on the data that Steve collected and published in the JFP earlier this year.

The other thing that I want to point out to you is that there's a pretty good R squared value there. It's on the order of .89. We actually added this to the risk assessment just earlier in the week. There isn't any variability associated with it yet. We're going to go back and do some regression diagnostics and try to incorporate some variability into this right now. Right now this just assumes a simple log reduction with no

uncertainty, but obviously the data warrant some degree of uncertainty.

So, to summarize, this program called Analytica uses a technique called Monte Carlo simulation to run a user-defined number of iterations on the conditions specified. I'm going to show you a figure in a minute which is going to be simulated numbers of E. coli in a gallon of cider for 1,000 iterations, so it would be like you took 1,000 gallons of cider, you varied all the different conditions according to the parameters that you set, and you'll end up with a range of possibilities for the number of E. coli you might find in that cider. And you're going to have a most common value and you're going to have extreme values, very high and very low.

The output of the simulation, as I mentioned, is this graphical output. You can also look at the--if you prefer numbers to pictures--you can look at just the raw statistics as well. And, as I mentioned before, this computer simulation could be run by anybody who downloaded the free Analytica Reader off the web and had a copy of our simulation.

Here's that figure I was talking to you about. This is the effect of pasteurization with all other processing steps held constant. We made a number of assumptions to do this. We assumed that there were birds

flying over our orchard which did contain 0157:H7 in their feces; that the farm in question was using animal manure; that there was no chlorine rinse, there was no freeze/thaw cycle, no preservatives used, and there was no cleaning or sanitizing of the equipment, so not a very well run operation.

And what you'll see is that obviously pasteurization, which is the green curve, shifts the number of log CFU of E. coli 0157:H7 per gallon of cider dramatically downward. What you'll also see, if you have a good eye for detail and you can read this slide, is that the shapes of those two curves are virtually identical. That's because as pasteurization is currently represented in our risk assessment, there is no variability or uncertainty associated with it. It's just a simple number of log reductions.

We know that there is some variability in the pasteurization process. In fact, I was up at Geneva this past week talking with Randy Worobo about UV pasteurization, and we're going to be--I'm going to be collaborating with him to get some handle on the variability associated with the UV pasteurization process, so that we can incorporate that variability into the risk assessment as well.

So this could be a typical example of the output that you might get from a risk assessment. You can see that most of the time you have a certain number of E. coli you suspect will be present, but in some samples you'll have more, in some samples you'll have less. Obviously, if we're concerned about a food safety risk, what you're really interested in is the upper end of the curve here or here, because that's going to represent a small fraction of the population of all the jugs of cider that we're selling that happen to contain a fairly high level of 0157:H7.

So, where do we go from here? Well, one of the real weaknesses of the risk assessment, and Art mentioned this when he called me on the phone and asked me to talk, was he said, one of his first questions was, "Well, how do you know, how does the simulation, where did you get your inputs for the number of E. coli on the apples that you're using?"

And the only way we could find to come up with that data was to make certain assumptions about contamination from birds and the number of animals in the orchards, the amount of E. coli in the animal feces, and we looked at defecation rates for animals. I mean, there was a really--there's a lot of assumptions underlying that, so we would really like better quality data there

to get--really to see if our simulation is accurate, or if it's not, to come up with better data on realistic levels of contamination on apples going into the process.

Certainly I think that all of the distributions, the statistical distributions that we're using, could be more accurate as more data are collected. And then finally I have validation listed on the slide with a little bit of a question mark. It's going to be difficult to validate a risk assessment as complex as this, but obviously that's going to be very essential, at least to validate parts of it, if this is going to be really useful as a risk assessment.

A risk assessment is really only as good as the data that it models. For example, we have lots of data on 0157:H7 in cow manure, more data than we could--almost more data than we could possibly want. That's a real good, solid part of the risk assessment. On the other hand, we have virtually no data at all on the effect of brushing on the presence of E. coli 0157:H7 on apples, so that part of the risk assessment is real weak. In fact, I think it's nonexistent. We don't have any data so right now that's not a variable we can include in the risk assessment.

So, to summarize, we think this risk assessment is a good start but it's only the first step. As I

mentioned, the work needs to be peer reviewed, and we need more data and better quality data. A risk assessment is almost never done. It's always a work in process, but--a work in progress--but it always gets better as you add more data to it.

And I would just like to leave you with one final thought from the statistician, George Cox. He said, and he's really right here, he says all models are wrong, but some are useful. We know ours is probably wrong in some places, but we hope it's a useful first step.

Thanks for your attention. I'd be happy to answer any questions?

DR. MILLER: Questions? Bill? Could you identify yourself?

MR. SNODGRASS: Bill Snodgrass, El Dorado. Could we go back to the slide there where you had pasteurization? There. The one on the right is where you take the worst case scenario, sloppy operation.

DR. SHAFFNER: Right.

MR. SNODGRASS: How far to the left does that move that if you don't have any cows in the field, you do not use the drops, you use all the sanitation? And one thing that you did not talk about was having a grade where you have a sound apple and that sound apple is

clean on the outside, it has been washed off, but there is decay on the inside, (inaudible.)

DR. SHAFFNER: Very good question. Let me answer the first part first. Where does the curve move if you change and you have good management practices? I invite you to, sometime this morning, come over and play with the risk assessment and find out for yourself. I don't know, honestly. It depends on a lot of different assumptions.

As far as the effect of grade and the ability then to clean that apple, if you know of some data that we can incorporate into our risk assessment, we would be happy to do that. I don't think we came across anything in the literature which gives us numbers.

I mean, you can't do risk assessment without data, and so if you have data that will help us to answer that question and we can quantify that and turn that into some equations or some distributions, then that can be incorporated into the risk assessment. If there's no data, there's no way to incorporate it into the risk assessment, except perhaps to ask a bunch of experts, "What do you think would happen if," and then you can incorporate that as expert opinion into the risk assessment. That's really the only way to do it.

DR. MILLER: May I just make a brief comment here? I only became aware that--Don and I have been friends for years--only aware for a month or so that he has been working on this, and I knew that if we could get Don to present this kind of talk, I'm sure every one of you has ideas fore new data sets that he can plug in. Now, if you don't have the data, but that's why we're here, to generate ideas for where we need (inaudible) data.

Once we have those data, then working with risk assessment by Don, then we can turn it over and add those modules onto his analysis, and in the end you wind up with a more realistic approach to quantitative risk assessment. So Don can only go with the data that he has in hand.

DR. SHAFFNER: And right now that's only data that has been published in the scientific literature as of this month.

MS. DUFFY: Last month.

DR. SHAFFNER: Last month, so we're one month behind.

DR. MILLER: To follow up on that, you weren't here yesterday, but the El Dorado County research project, there were a lot of people who came. Some of

the people who came shared some part of their research, shared some promising numbers, especially (inaudible).

DR. SHAFFNER: Great.

DR. EL-BEGEARMI: Mahmoud El-Begearmi, University of Maine. Can you look in the future, as our information improves, that we could use the model to (inaudible), see the circumstances and then based on the model, we could decide in this particular location, this is not pasteurization but something else, and it could be implemented to produce the results desired for safe cider?

DR. SHAFFNER: I sure hope so. That was one of the reasons why I got into this project in the beginning, was that it seemed to me that if you did a whole bunch of little things right, you wouldn't have to pasteurize. And that's what I hope to do, is to try quantify the effect of all of those little things. So if the risk assessment is good and it's sound, yes, it will let you do that, and that's one of the reasons why we got into this business.

DR. EL-BEGEARMI: That's a decision-making process that's based on knowledge rather than speculative.

DR. SHAFFNER: Absolutely, absolutely.

DR. HIRST: Peter Hirst from Purdue University. What are the interactions? Does this kind of model assume that there are no interactions between the risk factors?

DR. SHAFFNER: That's a really good question, and it's one that I've been thinking about over the last couple of days. Let me restate the questions so that you folks understand it.

He says that the risk assessment--and he's correct--the risk assessment doesn't assume any interactions. And this is an area where validation is going to be very, very important because right now if you have two steps, let's say there are two papers that have been published in the literature, Process X and Process Y. Each of them produce a 2 log reduction. All right?

When you put those into the risk assessment, each of those contributes a 2 log reduction, but those were two separate studies that studied those two processes independent of each other. Who is to say if, instead of using those two in parallel, if you used them in series, will you really get a 4 log reduction?

The risk assessment is only as good as the data that goes in, and if indeed you use Process X and Process Y, and it's 2 logs and 2 logs and together it's only 3 logs, unless you have a paper that has shown that

interaction, you can't incorporate that interaction of that into the risk assessment.

Now, maybe as we learn more about interactions of these different methods, we can learn where interactions are appropriate and where they are not. But that's a very, very good point and that's a very important caution, is that we are assuming all of these effects to be additive, and indeed they might very well not be additive. It's a very good question.

MR. SNODGRASS: Bill Snodgrass again. I have another question. How would you, taking the current 5 log reduction threshold, how would you take and measure, for example, if you remove the drops from your analysis, compare it and give that a number or a quantitative (inaudible)? Say this is a single treatment to get to your 4 log kill. How do you combine the two to get to the same safety level of a 5 log reduction?

DR. SHAFFNER: What you would do is, you would construct some graphs like this. Okay? And you would say, "Well, okay, here's my unpasteurized, here's my pasteurized, I know that's a 5 log reduction. Well, here's my unpasteurized. Here's the curve with taking out the drops. Here's the curve with the steam process."

And then you would look at the way that curve shifts down that direction, and as you shift it that

direction, eventually you would see, "Well, okay, I feel comfortable enough that I'm achieving a 5 log reduction." Again, from--that's what the simulation has done.

So that is, indeed, again why we got into this business, was to hopefully be able to show what we suspect the effect would be of adding these factors together.

DR. MILLER: Other questions?

DR. HIRST: Peter Hirst from Purdue University again. Don, when you said that you started out on this and thinking that if a particular operation was doing a lot of small steps right, then maybe they would combine to achieve the 5 log reduction with further development of this model, I guess there's one (inaudible) with the folks from FDA here. Would they accept that? If a particular cider operator does everything that's going into this model and says, "Hey, we're getting 5 log reduction."

DR. SHAFFNER: Do you trust computer models, Art?

DR. MILLER: I trust computer models as an estimate and as a guide. We're wrestling with this, you know. I missed Don's opening statement, so I have to apologize to the group here. One of the things that we need to bear in mind is that what we're really talking

about is risk analysis, and risk assessment is one piece of that.

Now, we're getting into the area of risk management, what do you do with the information? And, you know, are you getting warm fuzzy feelings or are you getting a cold spot in the pit of your stomach, thinking that the guys up the Hill over there are going to bring you before them and say, "What are you guys doing, using computer models to protect the public health?" Weather's okay. We don't know too much about computer models.

The bottom line really is that we are indeed very interested in risk assessments. In fact, right now in this agency we are conducting a risk assessment with Listeria monocytogenes. We have another one ongoing on (inaudible) in raw mollusks and shellfish. We work with USDA on E. coli. We work with other agencies on a variety of risk assessments.

So we are moving in that direction because it can serve as a guide. Is it the answer to everything? Certainly not at this point. But I believe, because I have a pretty big stake in this in my professional career, I think this is the wave of the future.

Think about the prediction of the weather. I mean, now we rely upon computer models all the time, and we make life-and-death decisions based upon these weather

facilities. So I think we'll be there, but we're not there yet. And remember, (inaudible) is only as good as the input (inaudible).

Questions?

DR. MATTHYS: Allen Matthys, National Food Processors. As I look through the models and see what you're putting in, they are achieving a 5 log reduction based on things that (inaudible), but many of these people are people that were using (inaudible), things that the entire industry would be doing to reduce total microbial load before we go into any further processing operation. That includes washing and culling.

Now, if you're getting a 3 log reduction there for everybody, you're really saying then that perhaps (inaudible) only part of a 2 log reduction, because the entire industry is supposed to be doing that anyway (inaudible).

DR. SHAFFNER: I think if you start from--

DR. MATTHYS: We need to know where is our starting point. What things do we expect everybody to do, and if we're going to do a 5 D or a HACCP, at what point do we start? Do you really start out in the field and start using that, or are you talking about some point up there after culling and washing and spraying, then

saying now you need a 5 D? And that's the decision that has not come forward yet.

DR. SHAFFNER: Right.

DR. MATTHYS: And you know (inaudible).

DR. SHAFFNER: And I think what you're talking about really starts from the wrong direction, though, because what you really need to consider--and this is a question for the risk managers, not for the risk assessors--what level of 0157:H7 are we willing to tolerate in the product? Okay. Microbiologists will tell you there's no such thing as zero, though.

Okay, so it has got to be a number, but this makes risk managers very, very touchy, though. They don't like to talk about numbers, but really that's what you need to do. You need to say, "What is my target in terms of what the end result is going to be? How many bugs am I going to want to have in the cider at the end of the day, what fraction of the time?

And then do the appropriate steps to reach that, rather than say, "Well, this is as clean as we can get it, and then we're going to lump on another five." I mean, we do that with candy. We say, "Well, how many bot spores can you stick in a test tube, and then let's kill them so that there's only one left," and you hope it's 12 D, you know.

So these are tough questions, and the more you get into risk management and the more you get away from risk assessment, the tougher the questions become, because they're not scientific decisions anymore, they're policy decisions. And I'm a scientist, so I won't comment.

MR. : (Inaudible), FDA. For validation I would like to see some data sets that were kind of set aside, that had nothing to do with going into the model, put them in the vault, and then show us these data sets that were not incorporated in the model, and then show us your graphs, predictions, what you actually got, I think that would be very useful. If you had some data that no one looked at to develop the model, put it away and (inaudible), that's real proof.

DR. SHAFFNER: And that's great. If anybody has those data, you know, when the risk assessment is done, then bring them to us and we'll be happy to run the comparison, absolutely. Absolutely. No argument there.

DR. MILLER: Anything else?

[No response.]

DR. MILLER: Don, I want to thank you very much.

With your indulgence, I would like to work off--do you all have copies of my presentation? I would like

to just follow along that. We have extra copies for those who need them.

MR. : (Inaudible) but I don't know what it is.

DR. MILLER: Well, my name is on it, Art Miller, and it was a handout from yesterday. We have extra copies. Does anybody need copies? Anybody else?

Okay. We asked Don to present information about quantitative risk assessment, and we know that there are data out there that either haven't been published, or the recent paper that I just read the other day in the July issue of the Journal of Food Protection that has some data that Don didn't encompass.

What I'm going to try to do is pull together what we know as of today in a non-quantitative way, but bear in mind what we would really like, what we would really like to do is work with Don. And, again, we only found out very recently that he's working in this area.

DR. SHAFFNER: I moved further away, Art.

DR. MILLER: But we know there are other variables that we need to consider, and that's what I would like to talk with you about, and I would like to do it in the following context. I would like to talk about some of the things we discussed yesterday in terms of the sources of contamination, and then what mitigation

approaches we have at our disposal today, and then try to get into this very fuzzy but very important question of how does it add up. Does it add up to five? Should it add up to five? Can it add up to five?

And, Don, I hope that I leave you with more questions than answers, because in my assessment, synthesizing this over the course of the last year, I think we still have an enormous distance to go before we really have a good handle on this issue. And then just finish up basically with an editorial comment and an invitation for participation in our project at Placerville.

Okay, what I have here are the list of sources that we know of, that at least have a potential for contributing to the problem of microbial pathogens on apples or in apple cider. And I'd like to just quickly march down this list, and in some cases review and in some cases mention what we know about these sources, and at the same time give you some sense in terms of the likelihood of these, of each one of these as being a source for microbial contamination.

Animals have been mentioned a number of times, but we can't exclude the fact that there may be a human problem as well. Organisms like E. coli, Salmonella, are both animal and human in terms of their source. When we

talk about things like Shigella, which as not been a problem with apple cider, that is totally human. So there are some microorganisms where you have shared sources. Others are very, very specific. And it really requires prudence to make sure that these sources are not a problem in orchards.

Insects and rodents, there is the one paper from the ARS group in Carneysville, the Japanese paper also that was mentioned yesterday about insects as a potential source. We know very little about rodents. Again, we don't have firm numbers on what is out there in the real world. We basically have a little bit of EFI and a little bit of laboratory data.

What is the role of damaged fruit? Gerry Sapers mentioned this as a potential source yesterday, either punctures or bruises. One point I would add that hasn't been mentioned, we do know that while an apple may be acidic, once it's bruised, that pH goes up. So any protection that pH would offer, at least in terms of growth inhibition, can be negated by bruises.

So what do we have in terms of current avoidance practices? Well, no manure. Try to keep animals out of the orchards to the best of our ability. Certainly possible, but where you can put up a fence, a fence would be appropriate for things like our friend over there

eating off of the tree, although deer can jump awfully high.

No dropped apples, and from our data at least, without--with natural background, we're looking at about a 2 log reduction. And as Bill Snodgrass mentioned, perhaps setting a minimum grade for fruit, again addressing the question of bruises and punctures and their associated problems.

Irrigation water can be another source of contamination, and we have virtually no data on contamination, at least in the apples. But certainly we know from our long experience in public health that contaminated water can oftentimes lead to contaminated food. In this country it's not a regular occurrence. Certainly in developing countries it's the first place you want to look. So we need to be very, very prudent about irrigation sources, water sources.

The other question that we don't know anything about is how you actually irrigate. Are there effects due to, in this case you see spray irrigation. What about tape and drip irrigation? Is one any better than the other? We don't know. We could use some information here.

Water use in plants. A paper that was alluded to a couple of times is a very recent paper in the July

issue of Journal of Food Protection from the State of Maryland, and one of the comments, if you wade through the mass of data in there, an interesting comment was the fact that apples coming out of the dump tanks had about 1 log higher total plate count than the apples going in. So we may be contributing to the problem, not solving the problem.

Many, many questions about harvesting practices, transportation, storage. When you have stacked transporting bins, if they've been on the ground, they can easily pick up soil, if an animal has been walking through, pick up manure, and when they're stacked that can be a source of contamination, as an example.

The question of drops versus tree-picks, we're starting to get a better handle on that. We know little about the effect with respect to storage, and we need a lot of data on that because so many of the apples that we have are kept in cold storage.

And once we get into the plants, there is an enormous amount of information we don't know. We're kind of nibbling at the edges. The literature suggests that the plant is a source of contamination. I already mentioned the paper from Maryland, and again, it's only one bit of data, but some of the work that Sue Keller has

been doing at Placerville again suggests that plant is also a source.

Sue didn't have a chance to talk about it, but just very briefly, when she was doing some studies with--challenge studies with generic E. coli, and put some air samplers around, she was able to find that strain. It was becoming airborne.

Another piece of this is again from this Maryland study, that suggests that the hammermill and the press also increase counts in the juice.

Another piece of this comes from work at Placerville as well as some anecdotal stories we've heard from the industry. There is actually a very poor correlation between the microbial loads of the apples going into the process and the juice coming out. That suggests that something in the process is confounding that. Are the organisms coming out in the components? Are they being introduced into the plant?

There is not a direct correlation between apples in, juice out, and we need to understand that better, certainly from a control point of view, because if we can't even do the proper research studies because we don't know where those organisms are being located--where they are located, then it's going to be very difficult to try to implement any true control measures in the plant.

We saw some information that Gerry Sapers presented about the effect of chemical washes, brushwashing, and there really isn't a lot we can say at this point. It doesn't seem to be that effective. Some of the treatments, at least in laboratory settings, are showing a 3 or less log decrease.

I would say, from what I've seen, that the hot water system may be the most efficacious. I know there are questions about energy cost, but certainly I think it's a low tech solution. You're not adding any chemicals, and I think it has enormous potential.

We mentioned the issue of internalization of the organisms, and this is from my point of view one of the most critical questions. Why? Because we are not going to be using the same technologies to clean up apples if all the contamination is on the surface versus contamination that's internalized. It will also affect where we apply the technologies.

And, again, we mentioned a number of sources, either the natural route through the calyx; or naturally, maybe an apple sitting up in the air with its calyx side up; or immersion in the wash water, and we talked about issues of temperature differential. How they get in, we mentioned those: the stem, the calyx, punctures and bruises.

I'll skip a couple of slides. I mentioned already that that paper from Maryland indicated that counts actually went up about a log as a result of the pressing operation. Given the complex nature of what we're doing, we're taking the entire fruit, crushing it and then pressing it, we're using these press cloths, there's an awful lot of work that we could do just around that single unit operation.

And then what happens after the juice is expressed? Certainly if the plant is a source of contamination, that means we need to be especially vigilant on this question. If you have open tanks, if it's not being properly refrigerated, we can have contamination enter, and I've listed just some of the technologies that we have to at least consider, and we've had a number of discussions about various technologies post-pressing.

And then, finally, the issue of workers. They need to be healthy, free of cuts and infections, of communicable diseases, practice good hygiene. The question of bare hands versus gloves may have a bearing here. They need to be trained on a number of matters, not only what the task is but on proper sanitation, to keep the area clean as well as keeping themselves clean.

Okay. Now, Allen mentioned this question, and what I would like to say is we're moving from science into the area of political science. What will it take to achieve a 5 log reduction? Well, what it will take depends upon your assumptions, and that's a moving baseline. That depends upon a lot of factors, some of which are technically based, others are not.

And I look at this really two ways: one, in terms of contamination and in terms of mitigation. And as I conclude my presentation, I will kind of keep them separately, but bear in mind that they are locked together.

In terms of assumptions, it depends upon where you are in your belief system based upon the reality of our databases. I tend to take the point of view that we have to assume that incoming fruit is contaminated and at least can be internalized, and that based upon a certain amount of data, additional contamination can occur in processing.

What we don't know, and Don eloquently stated this, we don't know what the variation is. We don't know the relative contribution of these sources, and that's absolutely critical to know, again, so that we can apply the right technologies; and then, secondly, at the right step in the process.

In terms of mitigation, these are assumptions: That efforts will be most effective if applied post-contamination, wherever that contamination is. If the contamination is in the field, well, almost anyplace downstream can solve your problem. If the contamination is at the point of pressing, it has to be downstream from that.

We're assuming, until proven otherwise, that the efforts can be cumulative. And previous talk, especially the question from--our questioner from Purdue put his finger on the issue. We don't know if in our assumptions we are killing the same bacteria twice. Okay? But we're assuming at this point that it can be cumulative.

Another point that I think is absolutely critical, and it really addresses the question of why we need to be vigilant at all steps, and that is, multiple interventions will reduce cross-contamination and lower microbial loads entering the processing plant. And I'll go through some scenarios.

If we have dirty apples coming into the plant, there is a better chance, assuming contamination occurs in the plant, that you have more organisms circulating in the plant. If you have lower loads coming into the plant, there will be fewer organisms circulating in the

plant. So any way you look at it, having a cleaner product being entered into the plant will be of benefit.

I wanted to go through some scenarios to get you thinking, and if you consider some of the points that Don had mentioned and then synthesize it with this, I hope to be steering your thinking towards a way of addressing where these intervention points need to be applied. What I've done is come up with a bunch of hypotheticals based upon the assumptions that I just outlined.

And if we look at the continuum from the orchard to the process to juice to the consumer, and accept the fact that we're not sure where on that continuum the pathogens are being introduced, so it can occur anywhere along that line. And if you follow down here the different scenarios, the X represents you have pathogens coming through, the "okay" means that it's below this magic threshold that we're striving for, the inverted triangles represent a pathogen source, and the green exclamation points represent intervention steps.

So, using my assumptions and going through these scenarios, you can see that depending upon where the points of contamination are and where the intervention steps occur, may or may not solve the problem for you. And just as an example, if we have no interventions and

we have pathogens, well, clearly you're going to be having a problem here.

In situation one we have contamination in the orchard and a series of interventions within the plant, including, and I'll just say no drops, culling, and some effective decontamination in the dump tank, with some post-pressing intervention. That would be okay.

If you have contamination in the orchard and in the plant, but all your interventions occur before that last contamination point, you've got yourself a problem. If your contamination points are before your intervention, and your intervention is effective enough, that's fine. And down the line. So, we need to be thinking again in terms of where the contamination occurs and where the interventions occur.

Okay, so if you add up everything I said for the last two slides, where does that leave us? If we assume that contamination occurs within the apples, that it's internal, and during processing, then we have to conclude that interventions applied after juice expression will have the maximum public health benefit. Again, we don't know this for a fact, but using those assumptions we have to come to that conclusion.

I was just told that we need to cut things short, so let me just--

MR. SCHWALM: Well, the next part of Art's is about the research needs, and I think that we can cover that kind of as a group when we talk about the research needs. We've got some other--other things.

DR. MILLER: All right. Well, let me just stop there. Do we have some time for some questions?

MR. SCHWALM: Well, flexibility needs to be the rule of the day here. I took my tie off because I developed a sweat here this morning.

We had intended to have Dr. Kvenberg kind of do a summary. I had wanted him to be here at the end so we could have some discussion and pull things together. We also have Dr. Buchanan that was going to share some of his thoughts, and he was going to be part of this panel, and to have him here.

However, at 10 o'clock these gentlemen need to be at a different place on a different subject which we won't get into. So what we would like to do here is to kind of change the agenda a little bit--we will still have the panel, still talk about research needs and so forth in a more organized way--but to take about a half-hour here and ask these gentlemen to come up and to just provide an opportunity for discussion.

The object of today was to kind of wrap things up, to talk about what our future needs, what our future

issues and concerns. I know that there have been some people here that have, during the course of the conference, have talked about, "Well, we really need to do this and we really need to do that."

This is an opportunity, I just want to open that up, not to debate back and forth or anything, but just to kind of get on the table concerns and issues and directions of where we want to go, while we have these gentlemen here, and then we'll get back to the panel in a more organized way. Does that sound okay? I see a few people nodding their heads.

Can we have John Kvenberg, who, as you all know, is kind of the head of our HACCP effort here; and Dr. Bob Buchanan, who is our science advisor, research person; and also who is not on our agenda, Joe Bacca, who is our new Director of the Office of Field Programs, and is very much involved in the interaction between our programs in the Center and the field.

So, again, the object here is just to have kind of an open discussion. And to let me start things off, I know there's at least one gentleman here that has a few things that he wanted to express, and that will give everybody else a chance to make some notes. So let me turn it over to our esteemed representative from Tennessee.

DR. BUCHANAN: Can I ask to make one quick statement?

MR. SCHWALM: Sir.

DR. BUCHANAN: We have--as you know, we are all in the process of developing the final form of the juice HACCP regulation. I wanted to let you know ahead of time, if you haven't already been told, that because we're in the process of developing a regulation, there are certain restrictions on what we're allowed to talk about in public during that process. In particular, what we can't do is in any way talk to you about what will be in the final regulation.

So if at some point we look like we're evading your comments, what we will do is just simply say we have crossed the line where we are legally not allowed to go because of the Procedures Act, and that way you'll know that we're not trying to evade your question. We're absolutely forbidden from talking about it.

DR. MILLER: I've had a request, too, that we use the microphone here.

DR. BUCHANAN: Okay. Now?

MR. SANFORD: Sanford from Tennessee. I know that's difficult to believe because I have shoes on, and I know it's hard to recognize me. As far as evading the question, I've dealt with FDA for 20-some-odd years, so

I'm used to FDA evading the question. Just kidding, no insult intended.

DR. BUCHANAN: I'll take it.

MR. SANFORD: I've worked with FDA for quite some number of years and have nothing but the highest regard and respect for a lot of the individuals I've worked with.

I'm in the field. Okay? I'm a mill grading officer. I'm one of those guys that's trying to make apple juice like milk. I get accused of this every day. All I'm trying to do is make it safe. I was asked to assess it, okay? So I want to address some issues, and really I'm just expressing some thoughts and issues. I work with some of the best academicians that I've ever worked with here at the University of Tennessee. They've worked with me. We've worked hand-in-hand with these folks.

Pasteurization. We have some of the top experts in fluid, beverage, continuous flow pasteurization within 300 yards of this building. Sure, it's milk, but some of the components are going to be the same, if not all. As of this morning at 8 o'clock, they have never been contacted for any assistance in pasteurization equipment.

I have people that I deal with in my area that are being sold, as I expressed yesterday, and well taken

and comments were taken down, I have people that are being sold junk by companies and they are told that it's pasteurization equipment. I have nothing to stand on. I can handle a vat pasteurizer, I can handle continuous flow, high temperature/short time, high heat, aseptic, UHT, any of those, work with them, understand them.

But I can get nothing to tell me what pasteurization is of apple juice. I have yet to see that. So that's one area that we really need to leap tall buildings in a single bound. And, again, those people are readily available and that knowledge is there, whether it's all of the components or merely part of the components. I know; they trained me.

Another area that I'm running into great difficulty, and it's not only with State inspectors, it's also with FDA investigators, and no disrespect intended in any way, form or fashion, those people's wagons are full. Okay? They may do a blood bank today; they may do a cosmetic manufacturer tomorrow; they may do a food processor the next day. Okay?

I go in, I'm asked to do a public health safety assessment of an apple juice processor. I go in, and I come out with three sheets of significant public health safety concerns, and I'll just go over a few.

Construction of the water supply. No water samples. No safe water supply. I'm talking about the processing, the in-plant water. Product contact surfaces, non-food grade PVC, soft copper, galvanized. Hydraulic fluid pumps for product with no sanitary seals; they're brass. Product vats that are half of a fuel tank off of a B-29 bomber, aluminum, that I can take and rub my hand and get spikes. Okay?

We talk about steam in process, but no one has addressed safe steam. I find steam, but we may be killing the organisms, but we're applying toxic chemicals from the descaler to the steam. We find cooling water in direct contact with product from cooling towers that's unprotected. We weren't told about Salmonella. Okay?

I made a list this morning. Let me see what I've done so far. And I've been trying to address this with Washington for quite some time, and I would--

DR. BUCHANAN: Now, we only have a short time.

MR. SANFORD: I would ask that Mr. Schwalm share with you folks the information that I faxed you last week, as far as the assessments.

Lead soldered joints. Rusty crushers. I'm talking about rusty as can be. Cleaners and sanitizers, construction degreaser for construction equipment, (inaudible) bleaches, those type things. So I go in and

I document this, and then I find out that FDA investigators have been there just previous, and their comments, and I've got copies of this, "No objectionable violations were found." I really have a problem with that.

And again, taking up for those people, they've not been properly trained. This is the only--you know, this is a very, very significant problem. It makes--you know, it leaves me in a situation, sort of, but I really have a lot of concern for those people. They're the ones that are out there.

So I guess that is my two concerns.

MR. BACCA: Can you give us, provide the examples that you've provided here and give me some list or something, and I'll take it up with ORA.

MR. SANFORD: Absolutely.

MR. BACCA: And if we can provide training, we certainly will. And I think if we're missing some obvious things that you're aware of, then we have to start looking for those things.

MR. SANFORD: I have taken it up with the district person there, been fully cooperative. I have actually been asked to put on some training, and have done that, with some of the investigators. And I run into some instances--well, I have full support at the

top, but in between there's some insult factors, because at no time--there's a law written somewhere, at no time can a State train an FDA person to do anything, if you know what I'm saying. And we need to move beyond that, we need to move forward.

MR. BACCA: In response to your other comment, I think we are going toward specialization, where food people do food work. We may not necessarily--while food people do food work, the food people may not necessarily do only apple juice, but they generally--you know, we generally try and keep them focused in one area. And hopefully by doing more of that we can get more (inaudible).

There's a limit to the number of people. That's our big limiting factor, and especially if we're going to be doing out of resident folks. You know, if they're not near a big city or a district office, it creates a problem. But I'll certainly take those concerns up with ORA management and see what we can do.

MR. SANFORD: I appreciate it very much, sir.

DR. BUCHANAN: Yes, and I do want to reinforce, and this is not the only location that we've seen this. Whenever we've gotten into the interface with what was traditionally--most cider producers did not think of

themselves as food processors. Most of them feel that they were agricultural activities.

But I want to make it very clear is that as far as FDA is concerned, these are food processing operations, and as such fall under the Good Manufacturing Practices that are required of any food processing operation, and so they will be judged on that basis.

MR. SANFORD: One additional question, if I may. Would all product contact surfaces, in your opinion, from the crusher on where we actually have juice, will they have to be safe?

DR. KVENBERG: Yes. I guess my response to that is yes, we would go to our existing regulations under GMPs, under 110, referring to food contact surface information, and that's pretty clear, we should be focusing on the cleanability aspects. It's clearly something that's known, and how to do it.

DR. MATTHYS: Was there a reason we did not cover 110 here at this particular session. There isn't even a copy of 110 in the documents here, and that should have been provided to the participants. It's a requirement that we're all having to meet.

DR. MILLER: This meeting was designed to talk about mitigation strategies. It was the assumption that

things are being done right. The question is, what can we do even better?

DR. MATTHYS: Don't assume too much.

DR. MILLER: Perhaps you're right.

DR. BUCHANAN: Can we get copies of 110 for them?

DR. MILLER: Actually, we were provided with (inaudible).

DR. BUCHANAN: Okay.

DR. CRASSWELLER: Rob Crassweller, Penn State University. The big question when I go back is going to be, what happens if a local grower--and this (inaudible), there is a 40,000 gallon discrepancy yet--but what happens if a local grower produces 5,000 or even less than 5,000 gallons and he keeps it all within a two-county region? What jurisdiction does FDA--and this is again for, it could be milk for that matter--does FDA have over that individual as far as rules and regulations on safety? Assuming he's going to do GMPs and everything like that, but can you come in and shut him down?

DR. KVENBERG: Well, I think that this goes to the legal question, relatively where does FDA have jurisdiction, and I don't think we're prepared to answer the discussion on this particular issue at this point in time. As a general rule, the Food, Drug and Cosmetic Act

has the ability to regulate interstate commerce, and there's a policy that you go to, to determine how far down the Act is applicable.

We're just not prepared to talk about that in the context of juice because we're in the middle of rulemaking, and this is one of the issues that Dr. Buchanan warned you that we really couldn't comment on this, but I know that is a sensitive issue. So we will defer on that particular point. But I think it's quite valuable that you bring up the information on this workshop to us as a concern.

DR. HIRST: Concerning the--you mentioned about the HACCP rule, and it sounds like there will be some kind of HACCP rule in some form. What time frame do you have in mind? When does it have to be finalized by?

MR. : This year or next?

DR. KVENBERG: Again, this is--I couldn't predict exactly, but the facts are that we have a proposed rule, we're currently reviewing the comments and redrafting the issue of the comments that we have received, and so we're actively in that process now. I can't give you a time frame for when the rule will become final.

I couldn't predict if--it has to go through, the process it has to go through is basically out of the

agency, through the department level at the Food and Drug Administration, through the Department of Health and Human Services, and then on through to the Office of Management and Budget. That's how rules are made. It's following the normal course, as other regulations do.

DR. BUCHANAN: And then just to follow that process up, then once it clears the Office of Management and Budget and is signed by the President, then I believe there's, what, a 30-day period that we could not implement, to give Congress the ability to look at it.

DR. KVENBERG: And then, not to make it more complicated, but I can draw you to several facts that were in the proposed rule, that were stated. And that is that there would be an effective date of the rule that would allow for its implementation, so it wouldn't be effective immediately. And as we had proposed the rule, it was basically staggered into large, small, and very small businesses, which would again stretch out the time frame for full enforcement implementation, if and when the rule becomes final.

DR. HIRST: So I'd be pretty safe in assuming there's not likely to be something to cover us for this coming cider season.

DR. KVENBERG: That's what I'm saying, yes. I mean, basically, I mean, that is just a logical extension

of what I said. I answered that, I guess, as best I could.

DR. BUCHANAN: You weren't supposed to. Yes?

MR. TAYLOR: Kirk Taylor, El Dorado. One of the backbones of a HACCP program is identifying critical points and establishing critical limits. Do we have enough established information to establish these points and limits that we have without (inaudible)?

DR. BUCHANAN: I think that part of Art's discussion here, and the last talk that I just caught the last moment on it, looks like some thinking on how you would go about identifying where your critical control points are. And remember, a critical control point is not only where the hazard occurs, but it's the step that you have identified for controlling that hazard, and there are different options for controlling hazards. That's the purpose of this conference. Different ones are being explored by different people.

So it's hard to give a single answer, but what we are looking for in any HACCP program is the degree of control that should be achieved and that --you know, the identification of that step or steps that are needed, and that you actually have those under control. So, yes, you're going to have to have critical control points.

MS. HUMES: There is a seafood HACCP program published. How specific is that, in comparing it to what might come out in the apple, as far as control points and what you have to say about it?

DR. MILLER: Could you identify yourself, please?

MS. HUMES: Oh, Lorraine Humes, FDA.

DR. KVENBERG: Well, yes, Part 123 is the one you're referring to, is the seafood rule. I guess you would--all we can really comment on is that we had a proposed rule put forward on juice, and the codified section is quite similar to but there are changes in the proposed rule from the codified rule on 123. And there has also been additional regulation as proposed by USDA's Food Safety and Inspection Service on meat products, so the processes are recognizable and similar but you have to read the rules and see how they are--there is some modification.

MR. SCHWALM: John, I think she's talking about the hazards guide, whether we're going to have something--

MS. HELMS: Yes.

DR. KVENBERG: So your specific question was, are we going to have a hazard guide? Well, regardless of the regulation, the question is, would we provide a

guidance document on juice products? My answer to that is yes. That's--my opinion is, we need to have a processors' guide in order to provide information for hazards and control guide information on juice. When and how we accomplish that is going to be something that we're going to have to get to.

DR. BUCHANAN: One of the commitments under the Food Safety Initiative is not only to do research, do risk assessment, et cetera, but to make sure that the knowledge that's generated and the information that's needed by everybody is disseminated to them in a form that's useful. So we have a very active program now, a very good team put together that will be able to get these messages out by different means and get them to the people that need them.

MR. SCHWALM: Yes, Gerry?

DR. SAPERS: Gerry Sapers, USDA. One of our (inaudible) conclusions is concerning the possibility that apples might be contaminated internally, and then it would be necessary to intervene with the juice, which presumably means some form of pasteurization. Have you considered the implications of this with regard to fresh cut or fresh market apples, if there is a significant risk of internalization of E. coli or other pathogens?

It seems to me that could be present in apples intended for other purposes as well as cider.

DR. BUCHANAN: Let me answer your question, and you have several different points there that need for me to go back and deal with. One is that the basis for any of our guidance and the basis for our regulation is sound science, and if a specific commodity is known to have a specific problem, that will be brought to bear in the development of any kind of guidance or regulations, etcetera.

So in light of the cut produce issue, and this is one that is not nearly as far along as the juice concerns, if the science leads us down that direction, that's the direction that we will be going. Likewise, as we sit and consider the issues associated with juices, we know that apples and oranges are not the same, and we will be bringing to bear the best science we have in looking at those differences.

Another point to emphasize here is that HACCP, the first part of HACCP is hazard analysis, where you bring your best science to bear to identify the problem, and it is specifically designed to be on a plant-by-plant basis because we know that no two processing plants are the same, so you want to be able to identify where you

think your hazards are and then make sure that you have the appropriate steps to intervene at that point.

Right now, with a lack of knowledge or actually with the knowledge that we have on potential internalization of bacteria and other microorganisms in apple products, we scientifically would have to work with the assumption that internalization of the organism within the intact food is a reality or certainly within the realm of possibility.

Did that answer your question, Gerry?

Yes?

MR. HAXTON: Bob Haxton, Iowa. And you may have already answered this question, but let me do it again anyway. The regulation on the warning labels for juice manufacturers who are involved in solely intrastate commerce, or how do you define intrastate commerce or interstate, and how are you addressing that? Are warning labels required when the manufacturer is only manufacturing for sale at that mill or that store?

DR. KVENBERG: Okay. The specific question, as I understand it, goes to the labeling rule and how far does it reach, and in essence that goes to the retail unit and therefore it goes--it goes, that rule specifically goes right down to local distribution.

MR. HAXTON: Okay, so if a cider mill is packaging and only selling at that site, even though their customers are only within a State, they would need to comply with that rule.

DR. KVENBERG: I'm not the legal representation on that rule, but that's my understanding, that it does apply.

MR. SCHWALM: We have about one more question here. Your question, Kirk? Go ahead, Kirk.

MR. TAYLOR: In the proposed regulation there was some (inaudible) for (inaudible) 3,000 gallons, or how many (inaudible), whichever, in the final regs?

DR. KVENBERG: There's no way I can comment on that one. There's a whistle on that one. We can't respond.

DR. BUCHANAN: We have received numerous comments about that part of the proposal. We are actively reviewing those comments and evaluating whether to keep that, but beyond that, we can't really say.

MR. SCHWALM: I've got one more here.

MR. BUSH: Don Bush from (inaudible). What is the rationale behind the 5 log reduction? Why not six or seven? (Inaudible.)

DR. BUCHANAN: The rationale for the 5 D, which was articulated in the proposed regulation and which will

be reevaluated, was based on the likelihood of contamination, the degree of that contamination, and resulted as a result of the public meeting on juice that occurred, what, almost two years ago, I guess, now, and then was reviewed by the National Advisory Committee for Microbiological Criteria for Food and then established, passed on to the Food and Drug Administration as a sort of a means of assuring safety while at the same time attempting to maintain the unpasteurized character of juices.

This is one of the areas for which we specifically in the proposed regulations received numerous comments on both the number of--the extent of the process, be it 5, 7, 12, etcetera, or 3--those seemed to be the numbers we had gotten in, or among them--and also where you start that process of counting. That is now being deliberated by the agency in making the final rule.

MR. SCHWALM: One more short one.

DR. BUCHANAN: Well, actually why don't we take the hand back here. This is a person who hasn't had a chance to comment.

MS. ZINN: I'm Leslie Zinn, Ardens Garden. We are a juice processor in Atlanta. And my concern is, and my understanding, that the large outbreak that spurred

all of this legislation to take place involved some negligent manufacturing practices, and several of the outbreaks that occurred previous to that large outbreak also included some very poor manufacturing processes. And I understand that, you know, it has come to light that juice can now carry these pathogens and it's a possibility that, you know, it can contaminate, make some people sick, but the risk-benefit analysis seems to be extremely low.

Now, as a processor, and we are all fresh, we don't have a problem with the compliance, but I am very concerned with this most recent outbreak that just took place, that we're going to be forced into pasteurizing, and it's not a cost issue, it's an issue that this is the niche of the market that we serve and this is what our customers want, and I'm afraid that we're going to be denied that opportunity to provide a fresh product, period.

DR. KVENBERG: I'll take it, I'll take it, I'll take it. But basically this has to--I totally understand your remarks and your concern of the current situation on an unfolding event as it's currently under investigation. So we just cannot comment on the specific rulemaking process that we are undergoing at this time, but I guess my only comment is, we hear your concerns.

MR. BACCA: And let me say something about that. With respect to the outbreaks that have occurred, when we find compliance, it has not been obvious what the failure was that led to the contamination. It has been something that, you know, if we had found it and, you know, been absolutely sure of what it was; it has taken an awful lot of digging, so it's not something that's right out there in front of everybody to look at.

MS. ZINN: Well, can you comment, I mean, I know that a lot of the information that has come out is that it was possibly processed not in the United States, and that it was part of something that was brought in. Is that what you all are finding, or can you say?

MR. BACCA: Which outbreak are you talking about?

DR. BUCHANAN: Are you talking about the orange juice outbreak in California?

MS. ZINN: Yes, the orange juice outbreak out in--

DR. BUCHANAN: That's one under current investigation. We really can't comment.

I did want to correct one thing, though. While the one outbreak did precipitate a large degree of activity, it was already well recognized here within FDA that there were concerns with unpasteurized juices. This

was actively being considered. It was not a single incident that led us to start this activity. There was a history of problems.

I might note also that we have done an extensive survey of the industry--I'm not sure if the results of that have been shared or talked about--that demonstrated a pattern of problems in a substantial portion of that industry, so--

DR. KVENBERG: Could I make a comment? We're at an unfortunate point in time where it's 10 o'clock and we're needed elsewhere. I guess it would be a last call, because we're going to have to terminate. The three of us are needed elsewhere. If there are no additional questions--

MR. SCHWALM: I just want to thank you. You've kind of taken Art and I off the hot seat, so to speak, because these questions have come up and having you here to listen, and understand that these are the people that are very actively involved with developing our policies and our positions, so this is a good opportunity. So I want to thank you all very, very much.

[Applause.]

MR. SCHWALM: Why don't we take a couple of minutes break, and Art and I can figure out what we're going to do with our agenda.

[Recess.]

MR. SCHWALM: If everyone could take their seats, I think we can get back on track. Okay, if we could bring everybody up to date here and get started, we're going to put Art back on. He had some more slides to talk about research needs, and that will then move right into our panel which we wanted to talk about future needs and directions and issues and that type of thing.

I'm not sure, in terms of labeling, despite assurances that somebody would be here, as I told you people, I have not seen anybody. I went by an office, and all the offices are dark, so I don't know what's going to happen with labeling. Maybe somebody will come over and we can put them on. So that's kind of an unknown right now.

So let us turn it back over to Art to continue with his research needs, and then we'll go with the panel.

DR. MILLER: Thank you, again. Okay, back to the program. I've been talking at this point to the question of what are sources of contamination and how can we mitigate the contamination, the hazards, and I broke a look at research needs along those lines of the hazard exposure and risk reduction.

And there are really two key points on the exposure side: What are the sources, and what are the levels? Because these have a significant bearing, again, on what technologies we use, where they need to be applied, and how intensely they need to be applied. Is it a 3 log, a 5 log, is it a 10 log, or whatever, reduction? Of course that is all related to the dose, how many organisms are out there.

On the risk reduction side, what are the technologies that are available to us, and then what can we do in terms of validation and verification?

With that as a backdrop, let's kind of break this down a little bit. On the exposure side, we need to know quantitative levels of naturally occurring surface versus internal contamination, and I have been dwelling on this point because it's absolutely critical.

If we have solely surface contamination, well, that will be one approach to solving the problem. If it's solely internal contamination, naturally occurring, we're going to mitigate the problem another way. If it's a combination, we're going to have to come up with an approach that will solve the problem, that will address both surface and internal contamination.

The processing, we need to know quantitative levels of contamination induced by the cider-making

process. I mentioned some of the information, a little information we have about how pathogens can be introduced and at what level during the processing and making of cider. We need to know quantitative information on it, though, because knowing where it happens and how much of it will determine how we reduce the risk.

On the mitigation side, risk reduction--Jim?

MR. CRANNEY: Jim Cranney from the U.S. Apple Association. A question: What kind of assumptions is the agency working on right now in terms of the probability level in terms of contamination? And what evidence is there that there--that that's a significant problem?

DR. MILLER: I heard two questions: What are the assumptions, and is it a significant problem? The assumptions--

MR. CRANNEY: No, what is the evidence that there is a significant problem?

MR. SCHWALM: If I can, unfortunately you've just had the opportunity. You weren't here, but we've already had a talk this morning about risk assessment.

MR. CRANNEY: Sorry.

MR. SCHWALM: And in--

DR. MILLER: Maybe we can talk about this afterward.

MR. SCHWALM: I think so, because this really is the beginning of his talk, which you also missed.

DR. MILLER: We're making the assumption that it can happen. In short, we're assuming that it can. What we need to know is, does it, and if so, how much? Short answer.

In terms of intervention technologies, we need to know how efficacious these technologies are, and we've heard about some research that is demonstrating just that. We need to know better, and again this question of contamination sources, where it is on the product, where we target these intervention technologies in the process.

And then the million dollar question: Are the intervention technologies additive or are they cumulative for reducing risks? Is the approach valid?

In terms of validation, we still have a number of questions about what is the best way to perform a validation study. How do you inoculate the apples? Are we going to get into a situation where we're going to count dead cells twice? Again, we don't know.

We heard a bit about surrogates, how we need to use surrogates. We need research in this area. Which ones do we use? How are they applied? How do you go about sampling your product?

One of the things we've done in Placerville is use different colored apples, where the inoculated ones are one color and the uninoculated ones are another color. Is that a reasonable approach?

And then how do we verify? Is it a record verification? Do we need microbiological verification? We don't know these from a technical point of view.

Who is conducting the research? We know that there is quite a bit of work at the State level, at the land grant schools, other universities. We know of research within the Federal Government. We heard of FDA research, ARS research, some of the contracts and grants by CREES. We also know that industry, especially equipment manufacturers, are sponsoring studies. We know of work that's going on that is sponsored by NFPA for example, out at their laboratory in California, and a number of consortia.

That kind of brings me to where I want to go with the conclusion of this talk, and that is the partnership out at Placerville. And I put up a photograph of our facility there just to show you that this is not pharmaceutical grade manufacturing, that we're working in real world conditions, that we have an excellent team working through El Dorado County, some of the folks in the back.

We have a very good support team working with the University of California at Davis. Linda Harris is here, a number of participants, including Gerry Sapers' group from ARS. Mary Wang, who is here from California State, working with Chuck Seizer, who you'll get to meet in a few minutes during our panel discussion, from the National Center for Food Safety and Technology. Sue Keller. There are a number of workers here. Valerie Davis, I don't know if she is here today.

But the point is that we have a team that's dedicated to working with the industry on resolving this issue. We've heard about some encouraging research. We have one example, Randy Worobo, who actually brought his technology to the plant and we trialed it there, and we would invite anybody that has some promising laboratory data to discuss it with us and we can make arrangements to have it trialed at the Placerville facility.

This is really a unique opportunity for research to be conducted in a real world setting. It's also unique within FDA, in that not only are we promulgating regulations but we're also trying to contribute to the solution of a problem by fostering research, and research that can be validated in a plant situation. The university has leased this plant and set it up for

research purposes. None of the product that comes out is used for human consumption.

So it's a unique opportunity, and I would invite everyone here to think about it. If you know contacts back home who may be interested in working with us on this, I certainly invite you to contact us about that. At that point I'll stop and if you want to discuss it, we can. Do we have some time for questions?

MR. : (Inaudible.)

DR. MILLER: Yes, fundamentally it's pretty much a turnkey operation. If you proposed a series of studies, Dave and his crew will make the juice to your specifications. Kirk and Linda and their crew will do the microbiology, so really what you need to do is set up a protocol, throw in a little bit of manpower, and our crew will take care of it.

So what we have tried to do is build the capacity to facilitate research. This is not grants, the way that you typically expect it to run at a university, but basically you provided the know-how and a little bit of elbow grease and we'll get the research.

Anything else?

[No response.]

MR. SCHWALM: Okay. Well, why don't we go into the panel, then, and invite our panelists up here. Why don't we put three on each side here?

The purpose of our session here was to or is to talk about where we need to go, what are some of the regional issues, you know, that would impact on how to proceed. It's like Art was saying, we continue to have the capability of research. We've been working on juice for some time now, but in many respects we're just starting. There continue to be a lot of issues and a lot of needs. Often when you do this type of thing, you get more questions than you get answers sometimes, and so we wanted to have an opportunity at the end of the session to kind of talk about where we want to go.

In order to do that, what we tried to do here is to structure giving some regional representation, and we have Dr. Beelman here representing the East Coast; Bob Tritten representing the Central States; and Dr. Mary Wang representing the West Coast. And we also wanted to get some industry representation, and asked Jim Cranney to come over here from U.S. Apple. And then we wanted one of our research people, which was Dr. Buchanan, and so we'll let Art kind of substitute for him, though he has kind of given his talk about where we need to

proceed. And we also have Chuck Seizer that was involved--I'm sorry--

DR. BEELMAN: We have a split team here, so I'm trying to figure out what we do with the mike.

MR. SCHWALM: Pass it. Chuck Seizer is from our facility, a facility that FDA utilizes in Chicago, and he can explain I think maybe a little better about the industry-government interaction and academia interaction with that facility.

If you gentlemen and ladies agree, if we could just kind of go right along with the outline here, and what we've asked is each person to make about a 10-minute presentation or so of their observations and opinions on the subject, and then we'll open it up at the end. I think it will probably be better to listen, to give everybody a chance to make their presentation, and then we'll open it up at the end for a general discussion. Okay?

DR. BEELMAN: Thank you. Actually, I don't purport to represent the East Coast perspective. When Art asked me to do this, I wasn't quite sure that that's what was involved because, you know, I can't represent the East Coast. I'm from Penn State but I don't, you know, know exactly what, you know, the--everyone on the East Coast would want me to say. So I'm speaking for

myself here, after observing what has been going on, as just an outside observer.

But the one thing that has come clear to me, at least, during the past two days is that I think we need some kind of a post-processing intervention. If the assumption is true that E. coli can be present in the fruit, which I think we have to presume, you know, I keep going back to the logic of canning low-acid foods, you know, the 12 D concept with bot.

We give that a 12 D process because of basically a risk assessment kind of situation over the years, and there really aren't very many bot spores on most raw food commodities. We still give it a 12 D process because of the safety situation. I'm not saying that it's analogous, but there are some lessons from history here.

And I'm not saying it has to be pasteurization. Some of the work that has been done on the freezing and warming I think is very encouraging. The UV pasteurization process I think is very encouraging.

The use of preservatives I think has been, for some reason, I think, underplayed. I see very little information about the use of chemical preservatives. I know Randy Worobo has done some work on preservatives along with the UV pasteurization. I don't know why he didn't present the data. I guess he wasn't asked to.

But it seems to me that we need some kind of a post-processing intervention, based on this paper that just came out from Maryland. That's basically what it says, is that a lot of these things that can be done in the orchard and washing and all these kind of things are useful, but the bottom line in that paper is that they can't be counted on to protect the public health.

So please don't assume that this is the East Coast perspective. This is my personal perspective, and of course I have a personal axe to grind because I'm working on preservatives, so you ought to realize that I have a--but I still think that, knowing what goes on at all these cider operations, and I've been to a number of them in Pennsylvania and other States, I just can't see the fact that all of the steps, intervention steps along the way that we talked about earlier, are going to be foolproof.

So I think I'll spare the time for the other people to make a presentation. I might reserve the right to come back and say something later, but should I pass it on?

MR. TRITTEN: Thank you. It indeed is a pleasure to be here this morning. Again, I'm Bob Tritten. I work for Michigan State University Extension as a horticulturist, and can relate to many of the people

who are here in the audience for the last two days, who are working directly with cider makers and have lots of questions that cider makers are asking when we're out at mills and out on farms, that folks are wondering what direction we're headed.

Gerry Wojtala, our representative from our Michigan Department of Agriculture, was originally asked to make this presentation and he was unable to be here today, so I was coming to this workshop and felt--and Gerry and I worked together on the handout that is in your notebook, to kind of draw together some conclusions about at least Michigan conditions. And I also don't purport to know all there is to know about cider making in the Midwest.

But, with that, I want to give you a bit of a snapshot of at least the Michigan cider industry and what it has gone through in the last few years, and then lay out some comments that Gerry and I put together with the help of or input from cider makers in the State who are part of a new organization that's forming, similar to one that has formed in other parts of the country. A cider guild is in the very formative processes of coming together in Michigan.

So I have a few comments, and I think one of the disadvantages of being on a panel and being so late in

the program is that some of these things, a lot of these things you've heard about, especially in Art's last presentation.

So our cider making in Michigan, it was really refreshing for me to hear on the last panel that we had here, that there is a recognition that cider makers really don't consider themselves to be food processors. They consider themselves to be, for the most part, apple growers who are also making cider, and they have also been making a product that has been considered safe for a long time, and therefore don't really think about themselves as presenting a product that is ready to eat for the consumer because it's cider. So it really is a mind-set that we're dealing with that is helping to stimulate a lot of the questions and is going to be a bit of a barrier to change along the way.

For cider in Michigan, starting in the '96 season we had about 200 cider mills that were licensed, and we do have a licensing program in the State. In the fall of '96 when the E. coli outbreak in the West occurred and things started to change very quickly in the cider business, 29 of them went out of business for the 1997 season. Another 28 didn't press cider in '98, and that really left us with about 140 cider makers.

Roughly 30 percent. I've heard other speakers talk about the number of folks that are not making cider. Of those 30 percent, some of them have decided that it was time for them to get out of business. Others decided that they didn't want to see the changes that were coming along affect their business, so they voluntarily pulled out.

Right now we have 14 pasteurizing units or heat treatment units in the State and two UV units that are up and operating, and that number is probably going to--not probably, we're looking at another 10 or so pasteurizers this year and another couple of UV units that look like they're going to be installed.

Just to give you a perspective, Michigan is a pretty large cider making State. We grow about 20 to 24 million bushels of apples a year, and we estimate--again, we don't have good figures
--that about a million to a million and a half bushels of apples go into cider making, meaning that we can produce about 3 million gallons of cider per year, so it is a pretty big part of our apple industry and it's also a big part of our fabric of who we are in Michigan.

Let me move on now to the research challenges that Gerry and I put together for cider making. These, again, were pulled together with the help of the cider

guild members and some calling to other folks around the country who are involved in the cider business.

First of all, and I'll run through these fairly quickly, practical applications of research, this is always a challenge but in the cider industry it is even more challenging, because the cider industry basically has been unchanged for so many years and had so little innovation and new practices that have come along, that cider makers really feel like they're being bombarded, and they're asking for a lot of the research work that people in the room have done, to take it to the next step and say, "What does that really mean at our cider mill? How can we take this information and make it apply to what we're doing?"

The second thing is, we need a benchmark of some sort to work from for measurement, and Art did a good job of really laying that out for us, but from a cider maker's perspective that's what they're asking for as well. What elements serve as our baseline requirements, and how do we determine if a mill falls within those requirements, is a major job.

Good Manufacturing Practices are something that we adopted in Michigan two years ago after a fair amount of struggle, and we have changed them every year since, adding things like no drops in cider, but we still have a

lot of holes in that Good Manufacturing Processes as far as taking the research, basic research work that has been applied, and making it work in that process.

We start really from the orchard and think about things like fertilization practices, irrigation practices, pesticide practices, and also try to take the approach from "bloom to jug" to producing safer cider, and we have a lot holes in our Good Manufacturing Practices that need a fair amount of research work, as well.

Number four, expanded selection of interventions to choose from, right now we have two early possibilities, one that is legal, thermal, and another one that is kind of in limbo, UV light, but there's got to be others out there. And we didn't really hear of much purposely about other research work that's going on that might apply to cider in Michigan. We have a promising researcher, Dr. Elliott Ryser, who has just joined our faculty at Michigan State, and he has been working on a sanitation project, for example, that he thinks holds promise for cider making.

And so there has to be--there may be--there are other possibilities for expanding the interventions. We've heard a lot about the freezing/thawing cycles.

These are good things, but again, how do we make those apply.

Number five, reliable sources of information is something that I have a hard time providing cider makers because it's hard to find information that we can take to them, that is in a form that they can use. Unfortunately, there's a lot of misinformation out right now in the cider industry.

Some of that is being promoted by companies that are making equipment. Other is coming from some of the juice manufacturers, that are saying that certain processes don't work, so there is a fair amount of misinformation, and it's a struggle from my perspective as an Extension educator to find reliable information that I can share with cider makers that can help them to make decisions.

Then we continue with number six, understanding the levels of risk, and this is a key issue for cider makers because they related to the Good Manufacturing Practices or GMPs. We want to know if we're going far enough with the GMPs. Are additional interventions needed, and how much is acceptable? We all know there is some risk, but at what level is that risk really a part of what we're doing?

Number seven, education, again a key area of mine, but a lot of components that we don't know about in terms of cleaning, sanitizing. Something we heard a little bit about yesterday, resistance, is that a possible threat in the future? I know it's a threat right now for certain fungicides and insecticides, providing resistance, so the fruit-growing community knows a fair amount about resistance, but not in terms of bacteria and other microbiological resistance that can occur at a cider mill.

Verification, Art did a good job of discussing that, so I'll really go over that fairly quickly. And then lastly, performance standards, what's really needed to verify what we're doing, and what kind of testing needs to happen? Is that going to be done by the cider maker, is it going to be done by a private group, is it going to be done by our Department of Agriculture, by FDA? So that's another area of research that I see or we see as a challenge for the future.

So now I'll close or turn over the microphone to our next presenter, but it seems like coming to a meeting like this, there's more questions right now than there are answers. We've come a little way, as I see it, in the process here of educating cider makers, but we also

have a long way to go in a short time period. So who's next on the list?

DR. WANG: I am. I speak pretty loud, so I think I can take care of it. Good morning, and it's a pleasure to be here. My name is Mary Wang. I'm with the State of California, Department of Health Services, and I'm going to use some analogy here because I represent the West Coast perspective, and of course I spoke with my counterparts in the States of Washington and Oregon, but I will be presenting the California perspective primarily.

But, anyway, sometimes you say, "Achoo." Now, I just sneezed. Well, guess what, who got the disease, the flu? Some other State. Somebody next to me. Well, in California what happened is, 1993 we had an outbreak but we didn't catch it. It was caught in the State of Washington, 1993, hamburger, E. coli 0157, and it was from a producer from the State of California. And so there was a lot of excitement going on, so what happened? Did you find it in the product? Well, later on we did, found it in the product.

At the end of 1993 we had the same thing in salami. Well, Washington State called us up. California produced the salami, and it was E. coli 0157. Did you find it in the product? You know. Yes, we found it in

the product. Well, that was extremely nerve-wracking, because where did it come from. Here we're talking about a fermented sausage, and of course salami is an uncooked product. It's raw.

In 1996, October, suddenly we got a call again. Says we got problems, we got juice, and it's a California manufacturer. Well, did you find it in the product? No, we don't have to, because we have good surveillance information, epidemiological data, and the statistics very strongly implicated that particular juice.

And there was going to be a recall, and of course the FDA found the E. coli 0157 in the product. They analyzed a lot of samples, finally found it in the finished product. That means it's very low level contamination. And they did a fingerprint match, the DNA, and it matched the patient culture. Unfortunately, one child died.

And so that was the end of October, October 1996, so in California all the small juice producers, the apple ciders, all of these got together. So naturally all of you know, California, or at least the West Coast States, we are major producers of apples, fresh produce, and fresh fruits and vegetables. We have a lot at stake.

But the primary goal for us is to protect public health. We don't want to cause diseases. We want to

eliminate that if we can, or the word is "prevention." We want to do something to prevent future occurrence of these things.

And so actually we got together, and one of the unique things that happened in California is, we have effective communication. I use that word because it takes a long time to get together with the local health departments and the Ag Commissioner's office, with other State agencies and with the Federal agencies. We developed partnership, and we decided that we need to speak with the juice industry, smaller juice industry.

So one of the most unique points is, we came together through public forum just like this here. So we talked. We stepped down and we listened to the concerns, some of the concerns the juice processors brought up. "We're small, and we have been producing juice for many years, and we never have a problem."

Then we have to share with them the information of the risk. How can an organism that is found in cattle as a reservoir, get on a fruit that's on the tree? And that's a question we haven't been able to solve in the scientific (inaudible).

So we listen, and then we share information about Good Manufacturing Practices. Now, most of the producers, they have three walls. They said, "People

like to come in during the cider season. They watch us press juice, they watch us bottle." So we tell them that if you are a processor, you need to have it enclosed to prevent any contamination.

And so that was one of the uniqueness, is we start talking with the small juice processor. Now, by talking with them, guess what we have found? We found out that these owners of these juice processors, they actually take pride in their product. They're very proud. They produce a quality product, and they felt they produce a product with minimum risk. And so that's not a unique thing, because they want to do something about it. They don't want anything to happen to the juice.

And then we got together. We felt that, yes, we should come up with some type of reasonable solution, and what is that? What is that?

So we started searching, and we saw the industry people contact other commodities. Around the State of California we have quite a few outbreaks, and all of you know that, in these different commodities. And there are several associations that have developed quality assurance programs, and these are a voluntary program which they have worked out with the academia, the government, the industry folks, that they would all come

together and develop the step-by-step control measures, if they can do that, that they will implement.

And so the third unique factor is, you have the processors that talked with us, the apple growers also came and talked with us. So here you have a diverse group of people, and these apple growers realize the juicers have to be assured that they are getting high-quality, tree-picked fruits, so they have to certify that as well.

So these three key points that brought this group together into a quality assurance program, and of course we need somebody to pilot this. Again, the group that decided that they will pilot and develop this program is the Apple Hill juice processors. Apple Hill is located in Placerville, which is 50 miles each of Sacramento.

And there is, what, 30 or 40 apple growers, seven juice processors that met, and they invited the academia, the government. And when we talk about government, it's the USDA, the FDA, Department of Health, Department of Agriculture, Ag Commissioner's office, local health department. We all sat down and worked out a quality assurance program.

Some of you have seen that brochure, and it is a HACCP-based program. It is not a true HACCP in the sense

there is no kill step. However, we recognized, and basically we did a risk analysis, a hazard analysis. When we got together, we said we didn't feel like we were doing hazard analysis, but we did.

And so we learned how to get Good Agricultural Practices or agricultural practices, whether good or bad, and from there we went to the processing end and Good Manufacturing Practices, practiced them. So basically it's a "bloom to bottle" concept, HACCP-based, and with the HACCP base there's training involved and there's record-keeping involved.

In fact, we even do a monitoring in the processing facility, because if they say they're doing a good job doing sanitation, how do you know? Okay, so we have the El Dorado County, they would have people to go there and check the facility. And we were invited to inspect the pilot in the fall of 1997, and they actually said, "Please come and do the inspection," and we did. The State, the FDA, we went and did inspection. We wrote them up for what the violation and they'll get it corrected.

And so that particular model, the way I look at it is, while we're still waiting for more research data, while we're waiting for regulation, that can be immediately implemented by a lot of small juicers. In

fact, the Apple Hill Juice Processors conduct several training sessions just before the fall season, and share with the small processors State-wide in the State of California.

And later on when I visited these different places in 1998, I noticed they have all improved their sanitation requirements, they have all come around and enclosed their facilities and complied with the GMP. It's slow, but it requires a lot of education.

So that's one I felt that that probably can be brought to all of you, that when you return, share this information. Some of you are State representatives. You can share information with the juicers in your State. Extension people can help out and develop what kind of research.

Art has extended the invitation about doing research. That is really a milestone, because as my grower had asked me many times, "Well, you know, if I don't use drop and we use tree-picked, don't I have a reduction of bacterial load?" I said, "Yes." "Well, do you have numbers?" "No." That's where we need research.

So through our discussion we come out with questions. Like you say, we have more questions, we need more answers, and that's where we all need everybody's help. Ask more questions. Thank you.

MR. CRANNEY: Thank you. My name is Jim Cranney, from the U.S. Apple Association, and I wanted to thank Darrell for the opportunity to come in today and say a few things from the industry standpoint. I have to apologize for not being able to be here earlier. I had another urgent regulatory issue on pesticides that sort of got my attention yesterday, and had several meetings over at EPA that I had to attend, and so I apologize for not being here earlier.

When Darrell asked me to make a few comments, he asked me to address specifically research issues that are important for the industry and what the orientation should be. And before I say specifically what those would be, I thought it might make some sense to just go back and look at this and sort of analyze really where we are.

When the first ruling came out on the cider labeling regulation, over the past--we've been dealing with that now for almost two years now, or going on three years, and essentially this issue really created a large change in the cider industry. And what has happened is, the larger and medium-size cider producers immediately converted to pasteurization.

So what we've seen is, out in the trade, in the industry, retailers and wholesalers of major supermarket

chains, what they did as soon as this became an issue three years ago is, they made it a requirement of their major suppliers to be able to supply what they considered to be a no-brainer, safe product, which means pasteurization. So essentially over the past three years what we've seen is that the major bulk of supply in terms of cider that's being processed in the industry really has been converted to, or at least you can say that there has been significant risk reduction from what we already had prior to the incident with Odwalla.

So, now, where does that leave us? That leaves us essentially with a group of primarily smaller producers, in many cases very small producers. So, I say that because it does have quite a bit of impact on the direction that USDA and FDA should take in terms of the research agenda that they follow.

So, without saying specifically what the research ought to be--I'll let that, you know, I'll let the researchers look at the whole spectrum of opportunity there, but I think it does have to meet some really specific criteria. And one of those would be that it should be practical and it should be simple for those types of producers to be able to implement.

So that means that as a researcher, if you get a very enlightened idea and it seems like a good idea to go

down the research path, but then at the end you come to the realization that it would cost the producer $20,000 or $25,000 to implement it, then I would say that it does not meet the criteria. Because most of these producers are probably looking at an area of between $5,000 and $10,000 at the most, because otherwise, if they were in a position to be able to expend that kind of money and dedicate those resources to the problem, there's a good chance that they would pasteurize.

So there's not necessarily a barrier out in the industry because the industry doesn't want to pasteurize. In a lot of cases it's an economics problem, but in another case there really is a demand for products that are not pasteurized, and that also has to be taken into consideration.

The other point that I wanted to make there is that when we're working with these small producers, I think we really--we really sort of get to a threshold policy issue here because we have to ask ourselves, are we really after zero risk? Is the goal zero risk? And if it is really zero risk, then maybe there isn't any other answer.

Maybe there is no other solution, and it is--I would say that what we're looking for here is a reasonable solution, and zero risk is not reasonable.

There is precedent in regulation that says that we don't have to have complete zero risk.

So, I think that there still is room for those small producers to be able to produce their product. Already the amount of cider that those cider producers are producing in the grand scheme of things is small, but it's important to that individual cider producer because they need it to sustain their own family and they need it to sustain their own source of income. And cider producers over the last three years have been hurt in that area.

So, I was not here previously for the discussion when you reviewed UV technology, but I think that if the agency really is interested in significant risk reduction, this issue, they should attack the petition that has been presented with significant vigor and expedite that petition, so that cider producers who are out in the industry who want to utilize that technology will be able to utilize it without fear of some type of an enforcement action. I know specifically that there are many, many cider producers out there who would like to utilize that technology, but for want of a regulatory hurdle, they are not able to incorporate it into their business.

My final point is not really research-oriented but it is communications oriented. I think that it is refreshing that we're finally talking about the science here and about data, and communication of science and data is important, and I would like to encourage the agency to go out to actually explain these types of issues to growers personally, and cider producers, who tend to be growers, at their winter meetings.

Unfortunately, many of the producers that we're talking about right now are--they're in the middle of growing a crop, and they're not in a position to get on an airplane and come to Washington, D.C. when they're in the midst of fighting off diseases and pests and trying to thin and, you know, get their operations in order to be able to actually harvest a crop.

So there is a significant amount of interest among producers to hear this information. They're very motivated. They want to do a better job, and I think that FDA could do a significant service to the industry if they went out to the meetings during the winter time as, Darrell, we've talked about this before, and presented a lot of the data that's been presented at this meeting, and I think it would be a big step forward along the lines of communicating and having growers actually

implement the practical risk reduction measures that can make a difference.

So, thank you very much, and I appreciate the opportunity to be here.

DR. SEIZER: My name is Chuck Seizer, and I'm the Director of the National Center for Food Safety and Technology. The Center, the National Center for Food Safety and Technology, is a group of companies, member companies--there are about 60 companies--the U.S. Food and Drug Administration, and Illinois Institute of Technology, and the University of Illinois at Urbana-Champaign, and we work entirely on food safety problems and food safety solutions.

After listening to all the discussion here, I think one conclusion is inescapable, and that is that there's going to have to be some sort of final intervention process in order to assure the safety of juice products, and there's a number of technologies that are out there that I think are pretty good candidates for being able to improve the safety of cider.

One that immediately comes to mind is some sort of light processing. UV light processing seems to be fairly inexpensive. As soon as the approval is through, it will be a very nice technology that even small cider producers can implement.

There are some other light technologies out there. There is pulsed light. There are people that are using exomer lamps, that are lasers essentially, that do a very similar job, but the cost of course is going to go up when you get into more sophisticated technology. I think that's one thing that we need to avoid.

There's also a technique called high pressure processing that's out there, where you take a juice and subject it to pressures of 60,000 pounds per square inch or higher. An advantage of this technology is that it will handle particles. It works very nicely for juice, and you get a product that is very, very similar to your raw fresh product. Once again, this is going to be a cost issue because the equipment is very expensive, and it would probably be prohibitive for most small cider companies.

Another technology that we have not looked at recently is the use of membranes to clean up cider, and you can effectively remove 100 percent of the microorganisms from cider using 0.2 micron membranes. The problem with this is that it also will make your apple juice as clear as can be, and it will not look like what your normal natural cider looks like.

And if you try to run that cider, you're going to clog your membranes in a matter of seconds, so you

have to go through some processes to clean it up. What you could do, though, is to take part of the cider that won't go through the filter and give that a thermal treatment or something else, and then mix it back in with unpasteurized raw cider and come up with a raw product. That would be one alternative for raw product, but there are some significant limitations.

That technology is coming along, so maybe in a few years there will be something available there. I think the area that is probably the most feasible is thermal, and I say that from two sides: One is removing heat, and the other is adding heat. The processes where you freeze cider look to be very efficacious, and likewise on the other side where you add heat and bring it up to pasteurization temperature look like they're very good.

One thing that we have to be careful of is that we don't try to apply dairy technology per se to the thermal processing, because that equipment is designed for milk and not for apples, and there's a lot of differences. For one, the plates are not going to be in contact because you have pulp that's going through there, and the pulp will hang up on the dairy plates.

Another obvious example is that you don't have a homogenizer in line for doing apple cider, and some of

the issues of control that go along with that. Likewise, especially for an aseptic operation, you're not going to want to have a flow diversion valve in the typical dairy sense of it, because that introduces a significant microbiological risk. There are going to have to be some adaptations of the technology for high acid, and high acid pasteurized products have an incredible track record, and we need to take some of the experience that they have and incorporate that into any guidance that comes out in regulations.

What else is left? Well, there is (inaudible) heating, you could use that. Pulsed electric field, fairly high technology, fairly expensive, probably not going to do the job for you. But overall, all these processes share a lot of common things that, number one, you're going to have to find out how to start the equipment up, how to get it sterile, put it in forward flow. We need to get it into forward flow so that we know the timing is correct, so that the product receives the processes it needs to receive.

We need to deal with control factors. We need to know what to do in the event of a deviation. For example, if you're running one of the light pasteurizing units and one of the lamps burns out, what do you do with that product? You can mark it down and try to sell it

today, or you can run it back through the system. So that's a real concern.

How do you keep records? And record-keeping is one of the things that small producers have the most difficulty with. You need to keep good records. When did you put the juice into freezing, how long does it take to freeze, how long do I have to wait before I pull it out? These are going to be questions.

And then the last issue, of course, is training. So I think the big job that we have ahead is to get some sort of guidance out for some of these new technologies that are available, and just to start getting the training going.

MR. SCHWALM: Art?

DR. MILLER: I've said my piece.

MR. SCHWALM: Okay. Do we have questions? Some comments from the people in the audience? What's your perception of our needs and directions?

MS. HUMES: A lot of us have said that it's the problems with the smaller processors, that they don't consider themselves processors, they consider themselves growers and cider makers. And another problem is the expense, and it seems like the suggestion is post-juice, you know, after you have made the juice, that that's where the intervention should come in.

Is there any way of getting some cooperative made up where the--and also logistically is it possible, where the growers and the cider makers could make their cider, chill it, and then take it to a processor that they have all paid for the expensive equipment, then do the intervention step, and then take that, or is that unfeasible?

MR. CRANNEY: I'm not familiar with every case that has happened across the United States at that level, but I am aware that there are arrangements that are going on along those lines, so I think that producers have been very creative in trying to find solutions where they would be able to escape the expense. So that type of approach has already been taken into consideration. Many producers around the country have been looking and trying to find ways that they could cooperatively work together. There are several of those types of arrangements already in action right now.

MS. HUMES: Because it seems like most of the pressure is on the people making the intervention, to make it cheap enough for this one little apple grower. It seems like at the other end, there might be some way to meet in the middle.

MR. CRANNEY: Right. Yes, there can be circumstances, though, that wouldn't allow for that, in

terms of--I think you need a critical mass, and in some cases you don't have that because a lot of those processors are selling small amounts just at their retail store, at their own farm market, for instance, and it would be difficult. Even the economics of doing that may not justify the expense of getting it together, transportation cost to get it where it has to go, and then even that has its economic threshold, but it is a good suggestion.

MR. SCHWALM: Anybody else? Let me ask you to identify yourself for the reporter.

DR. WALLS: Isabel Walls, National Food Processors Association. I was interested in your comments on preservatives, and I wonder if you looked at any beyond benzoate and sorbate for the effect they would have?

DR. BEELMAN: Actually, I have. Do you want to see some graphs?

DR. WALLS: Yes.

DR. BEELMAN: I didn't want to show this because Art said you were doing only--this was only on-the-shelf technology, and--

DR. MILLER: Go ahead, Bob.

DR. BEELMAN: Can I do it?

DR. MILLER: Sure. Why not?

DR. BEELMAN: Again, this is very, very preliminary. It's research that is ongoing, but--so there's going to be a quiz on this pathway at the end of this session.

This is actually the pathway by which mushrooms--and that's where I spend most of my time. That's why I can't speak on the East Coast perspective, because I've been down in the mushroom caves too long. But this is a pathway, which mushrooms form this compound, called 1-Octen-3-ol, which smells exactly like mushrooms. It's probably the best example of one compound smelling like a food.

And we were doing some research on this a number of years ago in our department and trying to figure out how we could make mushrooms produce more of this, and we weren't getting very far. And one day we were sitting around wondering--this is the so-called byproduct that's formed from this. This is an enzymatic, natural process. If you just start slicing up mushrooms, you could start to smell this, and this reaction would be going on.

So we began to think, well, what's this by product which has this hairy name, 10-Oxo-trans-8-decenoic acid, which we call ODA for short? And we actually have a patent on this as a fungal hormone, because it makes--we think it's involved in the fruiting

of the mushrooms. But one of the things interesting about it is, it's basically a 10 carbon fatty acid.

And that was another part of my research was, over the years, was looking at decenoic acid and similar medium chain fatty acids as preservatives, and they are very effective antimicrobials at low levels. But the problem is, when you get up to levels where you do get antimicrobial activity, 10 ppm and above, you can begin to smell them. They smell soapy, which isn't of course very good.

So we've been trying to find similar compounds to decenoic acid that don't smell bad, that have antimicrobial properties, and one day it just came to me that perhaps this might be one because basically it's a 10 carbon fatty acid derivative. So we started doing experiments, and we have a project at Penn State, Steve Knable and Rob Crassweller and myself. It's sponsored by the Pennsylvania Department of Agriculture, to look at methods to improve cider safety and education, and Steve and his group are working on washing techniques and everything, and I've been looking at preservatives, natural preservatives, ones that would be potentially natural.

So we decided to do these experiments where we put--basically these are test tube experiments where the

cider has been frozen. It was untreated except for the fact that it's been kept frozen. We thaw it out, put it in test tubes, add the preservatives, inoculate it with the E. coli 0157:H7, and this is the Odwalla strain, and then hold it for some length of time, and then measure the remaining cells.

And these are log reductions. Okay? The reduction of E. coli 0157 in logs. So what you're after is the 5 log reduction here, where you could be. And this is what happens, and in this experiment we warmed some of the cider to 45 degrees for 20 minutes, after the preservatives were added and after the bacteria were added. So this is what you get after 24 hours with nothing, less than 1 log. This is what happens if you heat it with nothing in it, and these (inaudible) are not different, so you get less than 1 log.

This is the ODA at 40 ppm with no heat. This is the ODA at 40 ppm with the heat. This is when you add the ODA with benzoate and sorbate, so this is the same as this, except that this one had benzoate and sorbate added, and you can see benzoate and sorbate don't do anything unless you heat it. And that's with the ODA, sorbate and benzoate together.

So if you either warm the cider at 45 degrees for 20 minutes in the presence of these preservatives,

you can get a 5 log reduction; also, if you're willing to wait three days, this number here is about 5 logs, the ODA with the heat. And so there are, I think--this is just one example. I know there are other people that are working on preservatives.

But for some reason the idea of using a preservative, I don't know whether that's a negative because cider producers don't want to use it, although the ones I've talked to, most of them use sorbate or something, and they say they have no problem with that and their customers don't seem to mind having a preservative in it.

So I think there's a lot of potential, for me, for the practical small producer. We're talking about something that's inexpensive, simple. If they had something, the cider producer, as soon as he jugs it up or gets it mixed up ready to jug, if he can put something in there that will assure his product is safe, that doesn't affect the sensory quality or whatever, it seems to me a very potentially useful, low tech kind of answer to the problem.

Again, I talked to Pat Hansen here about what, you know, has to be done to get something like this approved, and of course that's a long, nervous process. But Randy, apparently, I was talking to him at Geneva a

couple of days ago and he said that they find similar results using DMDC, dimethyl dicarbonate, which is a--I don't know if that has GRAS status for this application or not. He also used sulfites, but I know that's probably a no-no. It's not permitted in apple products, as far as I know.

So, thank you for the question. I didn't plant that, but I was hoping there would be an opportunity to show the data. Yes?

DR. CRASSWELLER: Rob Crassweller, Penn State.

Jim, just for the benefit, I know what some of these people have done, but just for the benefit of everybody here, how many States would you estimate have implemented some sort of GMP, GAP? I know Michigan has done it, Pennsylvania has done it, Tennessee has done it. How many other States would you estimate have done that, as far as response, so that we can get an idea of what the cider makers are really doing, and what the potential was before this, and now what it might be afterwards?

MR. CRANNEY: I can't think of any States that are significant cider producing States that haven't tried to do something in terms of educating their industry, coming up with some type of certification program, holding workshops. I think that just about every State that's producing cider has made significant strides,

trying to make progress in that area. So it's increasing the awareness and hopefully it's decreasing the amount of risk that's out there.

DR. CRASSWELLER: Does FDA take that into account?

MR. SCHWALM: Mary?

DR. WANG: No, you go on and answer. I have something I want to add.

MR. SCHWALM: Oh, okay. That's kind of a difficult question to answer, in the sense that, you know, part of the purpose of this session here was not necessarily to talk about survey data in the sense of States have been out doing inspections and sampling, we have done inspections and sampling. The inspections that we did back in '98, we did--

DR. CRASSWELLER: Ninety-seven?

MR. SCHWALM: No. I'm sorry, '97 I guess it was, because we issued the report just this year, and we did 250-some inspections. And, you know, what we found is that there are, in most places, minimal interventions, kind of like has been discussed here. Washing, maybe, and not much more than washing, on a general sense around the country.

So the data that we have when we went out to do our inspections does not support the fact that there has

been a lot of activity in the industry. Now, that was perhaps a little early in the cycle, and hopefully in '98 and this year that will change.

Part of the problem, of course, is how do you go about changing that? You know, we've kind of heard that yes, washing maybe will help a little bit but that's not the answer to your game, and sanitizers, there is very--when we were doing our surveys, there was very few people that were using sanitizers or anything, relatively few people that were using any type of preservative.

So it was, what we found was minimal intervention. Our samples that we took demonstrated that what you kind of start off with in the product is what you end up with in the product, so there is not--it's difficult to establish a correlation. There was a loose correlation between that.

So our data was--we also looked at data that was presented to us from some of the States, and that data was not inconsistent--it was consistent with what we had found. But again, that data was back in '97, and we have not done anything since that time. So some of the State people want to say something? Mary?

DR. WANG: Well, I just want to expand a little. The sanitation GMP, that's the basic, but then when we develop the HACCP-based QAP, we kind of bring them up

another level, and you keep bringing them up and up. And like your water, the sanitation, you know, they are at different places.

Some people pour a jug of chlorine in and that's it, you know, the bleach, household bleach. But then they realize they need to monitor and they probably should get the ones that are approved for washing fruits and vegetables, washing apples, and then they start monitoring their water level and maintain it. And then changing their water, I mean, there were people who never changed the water.

So these things need training, education, and eventually they can move up to--the way I have explained to a lot of the smaller producers is, when you produce a ready-to-eat food and there's no kill step, then every step is a critical control point, and that's where we start learning. Every single step becomes a critical control point.

MR. SCHWALM: And I think we've heard, too, that from some of the discussions and presentations, that the issue that we're facing here with the small apple cider businessman is more than simply a sanitation and a technical issue. I mean, we've got, the States have got the guidelines. We know something about equipment. We

know about contact surfaces. We know about vectors and insects and that type of thing.

The problem is, as we've talked about, is that they do not consider themselves to be food processors that need to apply these things. I could have flashed pictures up here of a barefooted processor that is standing down, he's got a jug of

--a gallon jug to fill with cider and a little block there, and the vat is coming down and the floor is right here, and he is in barefoot feet and, you know, he's filling up his jug, and that's what his customer wants. I mean, he does not consider himself to be a food processor.

So there is this other dimension. We can have, the States can have these regulations, and certainly there are some producers out there that are doing it, but the problem I think is beyond--there's dimensions of it beyond that, just whether we have GMPs at the State level or not.

And I think that very frankly, you know, the comment here by our other person from Tennessee about his frustration going in and doing inspections, I think that is a legitimate problem. I share it with him, and I'll share that the inspections that the FDA people do, I was

surprised at how many inspections that we did, that they did not find any objectionable conditions.

And, again, I think that that's a training type of an issue. We, normally FDA people are not going down into the States, into these small operations, and getting actively involved in trying to, you know, enforce GMPs at what are traditionally State places that are--you know, it's the State's jurisdiction and the State is bringing into compliance.

Maybe that's another thing that we need to do with the talks in terms of partnerships, of bringing the Federal, bringing the State together, and kind of agreeing that we are going to enforce a minimum level of sanitation. We are going to go out in this industry and, you know, we're going to enforce it, we're going to take some legal action, we're going to do what is necessary to enforce it. I don't think the States have made that decision. I don't think FDA has made that decision yet.

MR. : Darrell, as a processor I can tell you that from the industry's perspective, you have the full support of the industry to go out and do that. I know in California, particularly after we developed a QA in our area that became a model for the State, I know Mary and Health Services did a wonderful job of going out and communicating all that information.

I think there's about 105 processors registered in the State. I'm very confident that a very high percentage of those processors comply with GMPs, have made dramatic improvements in their sanitation procedures, and we welcome a very high level of inspection and enforcement by Health Services. And I think generally speaking throughout the country you would see that kind of support from industry. I don't know what Jim's perspective is on that, but that's our perspective.

MR. GARCIA: Garcia, Food and Drug. In the instance of inspectors, I can see that when you're dealing with apple cider, you're still dealing with a raw agricultural product, and if you go into a plant and you try to find insanitary conditions, you have to be reasonable in your write-ups simply because it is still a raw agricultural product before pasteurization. I cannot see where anyone can go in and try to treat it like it's a sterility drug under those conditions. You are there, the apples are right out of the barn. I can't see how we can train inspectors to see a different paradigm in that.

MR. SCHWALM: And I think this is in part why FDA is looking to HACCP as the--kind of the approach to address this problem, because through HACCP we look at changing the mentality, changing kind of the strategy of

the mentality, if I can use that, of everybody. You know, by doing the hazard analysis, coming up with critical points, having records, that that whole system will raise the level of sanitation, and that's in fact what we have found through our HACCP pilot program as we have worked with a variety of companies that have adopted HACCP.

In every situation the GMPs, the basic prerequisite programs, the level of sanitation has increased and has improved in those firms. Most of them, they were good at the beginning. It wasn't really a problem, but they have improved beyond that because it's very quick that they understand that the more that they control potential hazards through the prerequisite programs, the less effort or the fewer CPs that they're going to have.

DR. MATTHYS: I have a question on that last remark. If you don't consider that--if you consider it a raw agricultural commodity, that you don't have to worry about those problems, if your inspectors walked into Minute Maid or Tropicana and they were processing this raw agricultural commodity and they had those types of conditions before they pasteurized it, you would be writing them up. Those inspectors would be writing them up. You would have a 483 (inaudible) for ages if you had

those types of violations. I do not see how you can treat that any differently, because this is a processed food. This is a processed food. It's going to consumers, and any mistake we make goes directly to the consumer without any further changes.

MR. GARCIA: But if the concept is total bacterial load, the consumer is going to get it and it's not a sterile product. Even the Minute Maid is not a sterile product, so there is a certain amount of you might say a double standard being involved.

MR. SCHWALM: Any other questions?

DR. LaBORDE: Luke LaBorde, Penn State. One of the--you mentioned that every point is a critical control point, basically, when you get into growing, a fresh-cut operation. It's kind of contradictory to--most of these people are definitely afraid of critical control points and HACCP. They don't want to hear about it.

DR. WANG: Wait. I said ours is a HACCP-based, not a true HACCP. I have--I'll answer two things. Okay? Regarding raw agricultural commodity, in the California law, that it is in its natural form, that is, in an unpeeled state. Whenever you cut it, chop it, crush it, that is processing.

That is clearly defined, so--and that's how we convey the information to these small juicers, you know.

Because they considered initially, when we were dealing with the county, because there's direct marketing, saying, well, they sell directly to consumers, and that's retail. That's not a wholesale manufacturer. Why should the State come in?

Then we realized, no, they are manufacturers. They are manufacturing because, some of them, they package the product, they bottle it for other brands as well. That's manufacturing altogether.

But back to your cases, you have to look at the meat and poultry GMP--the HACCP. You have to look at the seafood HACCP. That's where the concept has changed from there. You have control points and then you move down to critical control points. And so commodities are very different. I just use that as an example when I talk with the small--when you produce a ready-to-eat food, you've got to make sure you pay attention to every step.

That's what the Apple Hill QAP did. We sat down and went back and looked at the apples altogether, I mean, you know, where you have the growers. How do you grow the apples? Can you do tree-picked apple? And the workers, the pickers, you know, how do they handle the ladder? How do--do they bend down and start doing this? I mean, all of these were put in.

DR. LaBORDE: Well, a traditional HACCP for meat, if you look at that it's a problem, because they say, "Well, prerequisite programs are important, but let's do the hazard analysis," and they're just off to the side.

So what we have done in Pennsylvania or what we're starting to do, is a hazard analysis that takes every step, mentions prerequisite programs as control procedures, and they may have to be verified and there may be record-keeping involved. There may be monitoring. But they are not critical control points, but you still get the same thing done.

DR. WANG: Yes, yes. Well, that's why we call it a quality assurance program, because we make them do records, too, and that's not HACCP. Go ahead, Bill. I'm sorry.

MR. SCHWALM: I just wanted to say one thing about why we invited the folks from California here, as just kind of a follow-up of what you're saying, what our discussion is. You know, how do we improve the sanitation, how do we improve the food safety within this apple cider industry, small producers? You know, there has been some discussion here about we need better enforcement, our inspectors to go out there and to become very critical.

We invited the Apple Hill people here because, you know, they have perhaps a little different model, and think Mary did very good at explaining that, and before when Dave was up here. But I think that this model of the regulatory people getting together, both at the State level, the Federal level and the local level, the industry getting together and coming up with a program that they have got buy-in with everybody, and the beauty of that project too was that they also had the economic incentive for the industry in the sense of promoting this quality assurance program to the consumer, to get the consumer recognition for that.

And, you know, the increased--or consumer recognition of that as a component of that, which helped the economics for the companies to bring that package together, seemed to be a very worthwhile model for other States and other areas to look at very closely. And certainly the sanitation level has increased in that area. It's not full HACCP, but certainly I think, as we said before, when we do have some interventions and we do know how to proceed with HACCP, you know, this Apple Hill group will be right there ready to go with that.

Now, you wanted to--

MR. SNODGRASS: Bill Snodgrass, and yes, that's just about what I was going to say. Let me reiterate,

what you're saying is correct. I can't remember the gentleman's name, but you are correct.

You have to understand my role. I've been working in agriculture for 30 years, and I am the county agriculture commissioner, so I'm not a grower but I do enforce regulations, so I'm (inaudible) at the top.

The industry came to me and said they don't trust FDA to do a good job, they don't trust the State Health Department, because whenever these folks walk into their plant, they have problems. So they came to me and said, and I'm going to be very honest, they said, "What can we do? We've got a real problem here. We're going to lose our fresh industry." And to them that's a very important segment of their market.

So then is when, because I know people at the State level, I went to the State Health Department, Stu Richardson, and said to him, "What's going on? You know, is there anything we can do here?" At that point we sat down, and I sat down as a facilitator, and I hope I don't offend anybody, but this wasn't--the term that was set at that time, all the FDA and the State Health people left their badges at the door, and they sat down and negotiated the Apple Hill quality assurance plan.

It was a very important term, a complete change in what the FDA has done in the past. They sat down and

were trying to assist the industry. Through that, the industry became educated and were saying, "Well, gee, I'm already doing that," and it turned out about 80 to 90 percent of the things that were in the QAP, they were already doing. And so, as Mary Wang said at one point, "Why don't you write it down on paper, make a record of it, and take credit for what you're already doing?"

And that's how the whole thing came about, and that's how the psychology of the industry has changed. And I don't think the psychology of the growers, our growing practices are different than on the East Coast, but the psychology of the growers is pretty much the same throughout. And I don't want to keep saying "California way" because sometimes California is put out there too much, that we expect everybody else to do it our way, but that's the way we do it.

MR. SCHWALM: Pat?

DR. HANSEN: I just wanted to respond to something that was said a little while ago--

MR. SCHWALM: Pat Hansen from FDA.

DR. HANSEN: Pat Hansen from FDA--about premarket approval and it being a long and arduous process. And what I wanted to speak to is that that is not necessarily true. I think it's very easy to walk around and say, as you might have heard, to complain

about having come in to us, but I dare say there is hardly anybody in this room who has actually dealt with our office.

There are a large number of folks who come in, share information with us, everybody leaves happy because we send them on their way telling them that they don't need to do anything further. They got reassurance. They learned something from us about the regulatory scheme, and we in turn learned something from them about what they're doing and what the industry is interested in.

Even if there are some things that need to be gone through, be it a petition or another type of process (inaudible) I was talking about, I think again the key is come in early. Don't wait to be (inaudible) before you come in. Come in early and talk to us, let us know what you're doing, what it is you're working on, what you're interested in pursuing. We need that (inaudible).

You may not need come to us further. You may need to do nothing else. You may need to look towards gathering additional data or information beyond the perspective you're working on, in order to satisfy some premarket requirements later down the road, but at least you would know early and we would have a good understanding from the beginning of what kinds of data and information that you needed to solve the problem.

I guess I would challenge people to take another view. Come in and talk to us early. Get some advice, get some feedback. I brought in today another handout which gives names and phone numbers of contacts in the Office of Premarket Approval, and I'll tell you we've got good scientists, we've got good people who know their science, know the policy, know the law. (Inaudible.)

MR. SCHWALM: Thank you. Now, we do have just the--just a second--we do have our labeling person here. Geraldine June is here to talk a little bit about labeling, so I just wanted to warn everybody here, because I think we've had some good discussion here and I don't want to cut it off before we're ready to cut it off, but just to let you know, and then Geraldine, that will be the last thing, and then we'll adjourn after that.

So, with that--

DR. HIRST: Peter Hirst from Purdue. I feel obliged to stand up for the small producers. In Indiana we have a lot of cider producers who make 10,000, 20,000 gallons a year, and five years ago they were doing practices that would make your hair curl up if you knew what they were, and there are probably a few of them that still are.

But it has really amazed me over the last two or three years how much they've changed their practices. Five years ago, the cider operation, it was a farm operation. Now to many of them it's a food processing operation. They take it very seriously.

And probably the best example of that is, a few years--I guess three years ago now there was a meeting. We had a representative of the FDA there to explain to the growers and the cider producers what the legal requirements are, what was coming along the pike, that sort of thing. That woman was lucky to leave the room alive. The cider makers were not happy with what they heard, and they expressed their unhappiness pretty candidly.

This last year at our summer meeting we had a representative of the State Health Department there, and again the cider makers were very unhappy with this woman, and the basis of their unhappiness was the fact that they wanted more regulations. They weren't happy with the--they wanted her to regulate, to put these people who weren't toeing the line out of business.

And so it just shows how much their mind-set has changed over the last couple of years, and so it really has changed dramatically just over the last few years.

DR. MILLER: Darrell, I wanted to get back to one point, I'll call it a point-counterpoint, on this issue of are we talking about a processed food or are we talking about a raw food, and I think we need to put things in perspective, particularly as I look at things from the FDA point of view.

We're dealing with so many issues, at least what I tend to do is try to bracket them, and let's look at some of the recent problems we've had in this agency with food safety. We've had problems with juice, we've had problems with sprouts, we've had problems with fresh produce, we've had problems with raw molluscan shellfish. What do these all have in common? They're raw foods. The problem is, they're supposed to be ready-to-eat foods.

And so I think what we're really talking about is the disconnect, call it a point of view, call it a paradigm, call it what you want, but we have people out there, be they inspectors, processors, or what, who think they are producing something other than a ready-to-eat product. And from my point of view, if it's ready to eat, it should be ready to eat, and it doesn't matter whether it's raw, cooked, or whatever. The bottom line is really public health.

And if we need to be going through a paradigm shift as a country, we need to realize that Americans are eating these raw, perhaps undercooked foods or underprocessed foods, but we need to put the prevention techniques into place to ensure that we can maintain public health and yet allow consumers to eat the foods that they want. So it sounds like we have a major education effort that needs to be invoked to make this happen.

MR. SCHWALM: And that may be a very good segue into labeling, because then that brings up the issue, can you inform the consumer that there is a hazard through labeling, and put the burden on the consumer then to make a decision?

So I want to thank our panel here, and invite Geraldine to come up.

MS. JUNE: Good morning. I'm Geraldine June from the Office of Food Labeling. I want to thank you for waiting until I could get here. I found out last night that I had to do the presentation. I wasn't prepared. I had just attended a funeral, and I didn't know I would have to come today, and I found out about 10 o'clock at night, so bear with me.

I want to talk about the juice warning label statement. We published a final rule in July of '98, and

that can be found in 63 Federal Register starting at page 37030. The effective date for that regulation was September 8, '98 for apple juice and cider, and November 5, '98 for all other juice products.

This regulation requires that fruit and vegetable juices bear a warning label statement if the product has not been processed in a manner to achieve a 5 log reduction, and I'm sure you all have already discussed what 5 log reduction means, so I won't go into that. But for purposes of our regulation, we defined "juice" as being an aqueous liquid expressed from a fruit or vegetable, and puree of the edible portion of a fruit or a vegetable used as a beverage, or any concentrate of such liquids.

So what products are covered by this warning label statement? They are any juice, 100 percent juice, or a beverage containing juice that has not achieved at least--that has not been processed in a manner to achieve at least 5 log reduction in the pertinent pathogen for as long as the shelf life of the product.

As I said, I'm sure you all have discussed in depth 5 log reduction, so I'll skip this slide. And I'm sure you all have discussed control measures. And the pertinent microorganisms are the ones that are most

resistant to being killed and the ones most likely to be found in a product if it has not had a control measure.

Some products are actually exempt from this regulation, and those are juice products that are not intended--that are, I mean, intended for immediate consumption. They have not been prepackaged, therefore contain no label, and these are products sold by the glass.

And the other exempt juice product is a juice ingredient where the manufacturer knows that it's going solely in the production of another finished product, or is going to be relabeled or repackaged. The juice statement is a consumer statement. Therefore, if the consumer does not seen the ingredient, that product does not have to bear the warning statement.

However, the manufacturer of the finished product needs to have that information. So would the repacker or relabeler. So in our regulation we allow that the information in the warning statement can accompany the product in invoices, bills of lading, and other procedures that are customary to the trade.

We've had a lot of questions about, where should I put my label on it? Is that an ingredient or does it go under finished product? The issue is, has the product that the consumer will drink been treated to get the 5

log reduction? If the juice ingredient is blended into a finished product, then that finished product would have to have a control step to kill any pathogens that may appear, or bear the warning statement.

And here is the infamous statement which says: "Warning: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.""

This statement was crafted on the basis of research from consumer focus groups. We did have a lot of questions about whether the juice should be labeled whether or not it is pasteurized or unpasteurized, and why does the statement use the term "pasteurized" and no other process.

And that reason is, we thought that was a statement or a word, based on the focus groups, that consumers understood. They don't understand, obviously, 5 log reduction or pertinent pathogens, but they have seen many products that said "pasteurized." So the point was not to exclude other processes, but to have a statement that consumers would understand.

The requirements for the placement of the label statement, it must appear on the information panel or principal display panel. I'm sure you know that the

principal display panel is the panel on the product as you look at the product to purchase it. The information panel is to the right of that.

This statement must appear in a box with use of hairlines similar to the nutrition facts panel, and it should be in a type size no less than one-sixteenth of an inch, and that is consistent with our standard food labeling regulations. The word "warning" should be in bold and capital letters to draw attention to the statement. So the prominence of the statement has been addressed by putting it in a box, capitalizing and bolding the word "warning."

In order to give manufacturers time to get their labels ready, we allow that the statement can appear in labeling. Labeling includes signs, placards and cards. And the type size of the statement in labeling is no less than one-fourth of an inch.

We allow that the warning statement appear in labeling until September 8th, '99 for apple juice and cider, and until November 5th, '99 for other juices, and these dates are exactly one year from the effective date of the final rule.

This was a question we received a lot when we finalized our regulation: Who is responsible for putting up the sign or placard? Basically, the responsibility

lies with the person whose name is on the product, which is the manufacturer or distributor, but the retailer is responsible for putting the sign up.

If the manufacturer provides that information to the retailer, the retailer just can't throw it away because they don't want it in their store, because doing so breaks the law. It's the same thing as if you took a label off of a can and threw it in the trash. You have misbranded the product, and therefore the retailer would be liable for breaking the law. Therefore, if the manufacturer has the sign, sends it along with the product, the retailer must display it in their retail establishment.

Okay, that's all I have. Do you have any questions regarding labeling?

MS. HUMES: Lorraine, with FDA. Are these labels to be put on the products, are they made within States as well as interstate products?

MS. JUNE: The labeling regulation did not address intrastate, and it's because food labeling regulations usually apply to interstate commerce. Under the Food, Drug and Cosmetic Act, the product has to be in interstate commerce.

DR. WANG: After September 8th, 1999, is it true that the warning must be on the label, no more placards allowed?

MS. JUNE: Correct. It must appear on the label after--

DR. WANG: On the container?

MS. JUNE: On the container.

MR. COLMAN: That was my question. You said the warning statement may appear on labeling until September 8th or November 5th of 1999. When you said "may appear on labeling," does that mean like placards?

MS. JUNE: Yes, that means placards and signs.

MR. COLMAN: Okay. I just wanted to make sure.

MS. JUNE: Yes. The label is the actual--

MR. COLMAN: Right. We've already got them on our product. I just wanted to make sure.

MR. BUSH: Don Bush. What about product going outside the country? If that isn't required in the country of its destination, does the warning label have to be on a product that's going out of the U.S.?

MS. JUNE: If it's--that's difficult--if it's going to be sold in another country, then the labeling requirements must comply with the requirements of that country. However, if that product is sold in some form in the U.S., then it has to have the warning statement;

but if it's not ever sold in the U.S., then it doesn't have to comply.

DR. MATTHYS: If it's going outside the country, the finished product, it will have to comply with the country it's going to.

MS. JUNE: Right.

DR. MATTHYS: So then the Canadian requirements would be involved. I would say while it is transported within the U.S., it's going to have to have that notice portrayed on it, or it would have to be pasteurized before it crosses the border, because it's still in the U.S.

MS. JUNE: Yes, that's still interstate commerce.

DR. MATTHYS: That would have to be the notice it hasn't been pasteurized.

MS. JUNE: Right.

DR. MATTHYS: But once it crosses the border, then (inaudible).

DR. HIRST: Peter Hirst from Purdue University. Is the warning statement on a separate sticker on the jug, is that acceptable?

MS. JUNE: Usually we allow stickers as long as they stay affixed.

DR. HIRST: Right.

MS. JUNE: And sometimes that's hard to do. In the printing of new labels, we require it on the label, and usually if you want to use stickers, that's fine, but you may have a problem if it falls off.

DR. HIRST: As long as it's on the jug, it doesn't have to be on the main display sticker. It could be on a different sticker at the top or something like that?

MS. JUNE: It could be on the information panel or principal display. When you say "main," is that the front of the package?

DR. HIRST: Yes.

MS. JUNE: The regulation requires that it could be on either one, information or principal display.

DR. MATTHYS: I think what he's asking is whether it could be somewhere else on the container, and I think the answer is no, it has to be on the label itself.

MS. JUNE: Oh, yes, yes. I'm sorry. Yes.

DR. MATTHYS: Either on the information panel or on the principal display panel. It can't be like a sticker on the top or something like that, separate from the label.

MS. JUNE: Right, right.

MS. SHALLO: Hilary Shallo with Praxair. Could you address the use of the word "fresh" on labels, and in particular the control measures over what can be called "fresh"?

MS. JUNE: Oh, that's a big question. We are actually looking into that right now. We have a regulation in 21 CFR 101.95 that addresses the term "fresh," and in that regulation it says that a product could not be processed or it could not be heat-treated or it could not be frozen, and it did give some leeway for certain procedures that may be done, such as cleaning or waxing, and I can't remember the others right now.

But when we came up with this warning statement and people started trying to use different procedures to kill the pertinent pathogens, we got the question, "Well, if we do not use a process that's not a thermal treatment, can we call the product fresh?" We're still working on that, because to allow one product but not the other would open up the whole regulation and we would have to deal with the use of the term "fresh" for all products.

And also we wrote the regulation in the belief that consumers would be misled if they thought a product was processed in some manner or preserved in some manner, and they thought they were buying a fresh product. But

clearly--and I actually received a call this morning that I have to return. A person asked if a product has been pasteurized, can it be called fresh food? Clearly you can't have a pasteurized fresh product.

But as far as the other treatments are concerned, we would have to look at those on a case-by-case basis and decide whether or not we would move to change our regulation or to have some provisions on which process you can allow, that this would still be termed fresh. Now, I probably didn't give you an answer, but at this point if it doesn't fit the regulation, then it cannot be called "fresh."

MS. SHALLO: How should we--should we approach your department, if we believe we have a technology, should we approach the Office of Labeling and ask on a case-by-case basis?

MS. JUNE: Oh, sure. Yes.

DR. MORRIS: If and when this UV light process is approved, will this label have to (inaudible)? Bill Morris from Tennessee.

MS. JUNE: Well, that depends on if the UV light procedure has accomplished the 5 log reduction. If it has, then the labeling provision wouldn't apply to it anyway. There would be other issues of whether or not the label has to say whether or not it's UV treated. You

know, that may be a separate issue, but if it has achieved 5 log reduction, you wouldn't need this statement.

MR. SCHWALM: Thank you very much, Geraldine.

I'm not sure where my co-person is over here. Is Art out there? Why don't you ask Art to come in?

I think we're at 12 o'clock. How do you like that? We're on time. I think it's hard, though, for Federal Government people that have an audience like this not to say a couple of words at the end. And Art, I'm not sure if you wanted to say something, but you know we wanted John Kvenberg to come in and do a little summary, but let me just say a couple of real short things in terms of what I've gotten out of this.

You know, the first thing is that when we put this conference together, we knew that this was not going to be one of those things where we had all the answers and we were going to present the answers to you. And sometimes the tendency of government is to wait until you have the answers and then to give the answers out type of thing. Well, that's not obviously the approach that we want to use here, and not the purpose of this conference.

But I think that we have all--including myself, because a lot of the stuff, some of the stuff was new to me--we have got an increased awareness of where we're at

right now, what are some of the issues and the questions, where we need to proceed, and I hope that you share with me the understanding this is not an easy process.

There is an effort and a concern about the industry, to preserve that fresh industry if that is possible. There is an effort and there is a concern about small industry, to address their needs if that is possible.

On the other hand, you know, we are producing a food product. There are public health issues involved. We also have, as NFPA has pointed out to us, a large part of the industry, and that if you have a problem with one company in the industry it affects everybody else. So it's not an easy problem. There's a lot of different issues involved here.

But I think that another issue or another thing that I've taken away from this is confirmation again that it all boils down to prerequisite programs in sanitation. This has been the source of our problems when we've had outbreaks and have problems, and if nothing else, the more than we can improve on the sanitation, bring that up. that that will--perhaps that's the best thing that we can do right now in terms of reducing the risk. And so hopefully, you know, we have a renewed commitment to do that type of thing.

It's interesting, in terms of risk analysis, everybody wants to say, "Well, what is the risk associated with this?" And yet that is to a certain extent a new technology in itself, and even though we may want to be able to do that, you know, to the extent that we can, it is questionable as well.

So those are some of the basic things, I guess, that I'm taking away from this. I'm really happy, and I think we were very surprised and very pleased, that we had such good representation. I want to take on the challenge that Jim Cranney gave us in terms of going out to the industry. Hopefully we will be able to do this, to bring a summary of this meeting together and the materials that have been presented, and maybe update these things, and to make sure that this information gets out.

But this is why we have given you each a procedures manual. We tried to pull this stuff together. We invite you to go back and make copies of it, and to talk to your local people, distribute it to your industry, talk to your industry, use this. Don't just rely upon FDA maybe being able to get out to these local meetings. I don't know if that is going to be possible. So please be our advocates here in terms of giving the information out the best that you can.

Art?

DR. MILLER: One of the lectures that I give has to do with the subject of emerging pathogens, and the whole lecture can be boiled down to the fact that we have an idea but not necessarily know where these pathogens came from. We have been doing things since we all emerged from the primordial soup. We've been eating. What has changed?

Here is a classic example. We have an industry who, as John Kvenberg said yesterday, has probably been with us since before this nation was a nation, and here it is in the '90s and we're suddenly concerned about this. What has changed?

We know that the pathogens have changed. In fact, we could probably say that the first outbreak that we're aware of, of 0157:H7, occurred back around 1980 in apple cider. So we know that pathogens change.

Are the sanitation practices, the practices of the industry, changed? Well, we know that there has been some consolidation and all that, but yet we still have an awful lot of small cider processors.

So you have to boil that down by saying we're not certain exactly how things have changed or what has changed or how much, but the fact is that we do have people who are getting ill as a result of this product.

And the bottom line from the FDA perspective is public health.

We called this meeting for the purpose of exploring new and promising technologies, and I think we have heard about a number of these technologies. We still have an enormous number of questions on where the technologies need to be applied, are they efficacious, and how and where they should be applied.

We tried to add some structure to this this morning by talking about this in the context of risk assessment and risk analysis, because that seems to be the way that we're moving. And just very quickly, we know that the research can't provide all the answers as fast as possible.

I think in my estimation the risk assessment allows us to stay ahead of the research, as we heard this morning, because that allows us to come up with the "what if" scenarios, and by coming up with the "what if" scenarios, we can then develop hypotheses that can be tested, so I think it's a very valuable tool.

And then, finally, as a result of these risk assessments, there is always that need for more research, and I think better than any other meeting that I have been through, we identified where the holes are. And I

think we have, at least in my mind, come up with a road map of how we need to proceed.

And on that note I will stop and wish you a good trip home?

MR. SCHWALM: Does anybody else have something on their mind here? We're not the only ones. Anybody else? Well, thank you very much for coming, and everybody have a safe trip back.

[Whereupon, at 12:05 p.m., the meeting was adjourned.]

- - -